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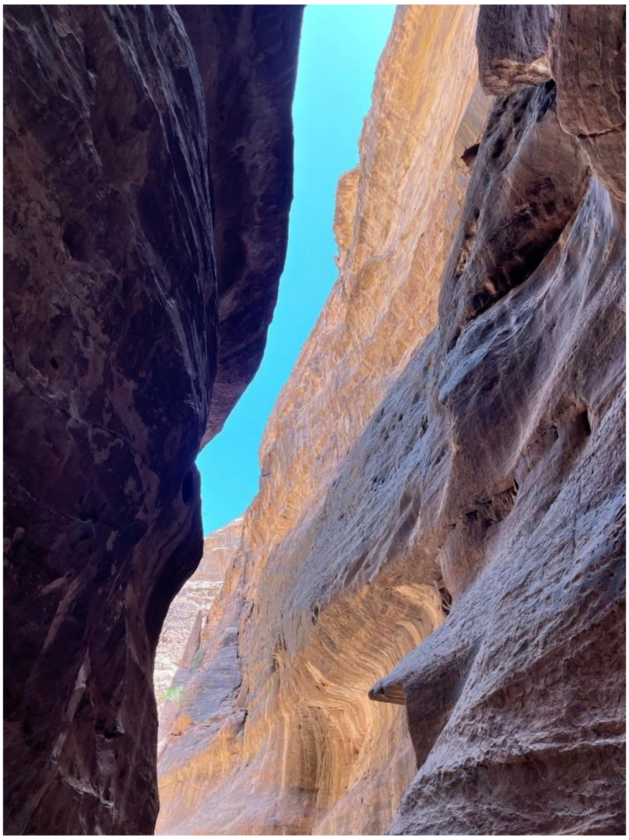

PhD thesis

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Project Meaningful Activities and Recovery (MA&R)

Development and evaluation of a peer co-led occupational therapy intervention

Supervisors: Tom Møller, Ulrika Bejerholm, Lene Falgaard Eplov

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List of papers

	Title	Authors	Status
1	Occupational therapy interventions in mental health: a scoping review of recent evidence	Kirsten Schultz Petersen, Siv Therese B. Bjørkedal Anne Marie Torsting, Lene Falgaard Eplov	Published in International Journal of Therapy and Rehabilitation, 2019
2	The missing link- Participants` perspectives on transfer from interventional contexts to everyday community life	Siv Therese B. Bjørkedal, Lene Falgaard Eplov, Tom Møller	Published in BMC Psychology, 2021
3	Meaningful Activities and Recovery (MA&R): the effect of a novel rehabilitation intervention among persons with psychiatric disabilities on activity engagement; study protocol for a randomized controlled trial	Siv Therese B. Bjørkedal, Ulrika Bejerholm, Lene Falgaard Eplov, Tom Møller	Published in Trials, 2020
4	Meaningful Activities and Recovery (MA&R) A peer co-led occupational therapy intervention for people with psychiatric disabilities. Results from a randomized controlled trial	Siv Therese B. Bjørkedal, Ulrika Bejerholm, Carsten Hjorthøj, Tom Møller, Lene Falgaard Eplov	Prepared paper for submission to Journal of Mental Health
5	“Moving on – to an open world” A Study of Participants Experience in Meaningful Activities and Recovery (MA&R).	Nanna Kaas Tepavicharov, Jeanette Reffstrup Christensen, Tom Møller, Lene Falgaard Eplov, Siv Therese B. Bjørkedal	Published in Occupational Therapy International, 2022

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Preface

When I was studying occupational therapy, I did my first training in a somatic hospital. Unfortunately, that did not go very well. I was told that I lacked communication skills and I was incapable of establishing therapeutic report with the patients. The occupational therapist who trained us students, said that if she could, she would have failed me. Upon this, I was ashamed and discouraged, questioning whether I was fit to be an occupational therapist at all. I felt nervous and dismayed when I entered my second training about a year later, in a psychiatric unit, at Bispebjerg Hospital. Since establishing trusting relationships, my Achilles heel, is the very core of all mental health practices, I was about to give up beforehand. My silver lining was that I met the occupational therapist who trained us, Helle Flindt. She listened to me explaining my previous training period, and never mentioned it again. Instead, she gave me the opportunity to start on a fresh page. She encouraged me, educated me, made me believe in myself again. *Rest is history,* as I came to devote my work life, to the field where I rediscovered my strengths and aspirations and found my professional identity.

This happened almost 25 years ago, but I have revisited my encounter with Helle, several times while writing up my thesis.

During my professional life, I hoped that I would get the opportunities to pay it forward, to help others in rediscovering their uniqueness and in finding their way. That I could become someone`s Helle. But how do you translate that into an algorithm, a logic model, a research hypothesis or even a clinical guideline in mental health practice? Are these essential things truly invisible to the eye[1]? Being part of mental health services for more than two decades, first as occupational therapist in an inpatient unit, later in a community mental health centre and now in mental health research, the same two questions puzzle me: Are we helping people with mental illness to recover their lives? How do we know if we are doing the right things? Entering academia, is my emerging attempts to provide scientific responses to those questions.

This thesis resolves around the development and evaluation of a peer co-led occupational therapy intervention called Meaningful Activities and Recovery, (MA&R) designed to enable occupational

[1] Paraphrased from the Little Prince, by Antoine de Saint-Exupery. Original quote: *"And now here is my secret, a very simple secret: One sees clearly, only with the heart; Anything essential is invisible to the eye."*(1)

engagement among people with psychiatric disability, and to promote personal recovery, functioning and quality of life. The thesis consists of four studies, reported in 5 papers

1. A scoping review to identify and assess the current evidence base, informing occupational therapy practice in mental health (paper 1)

2. A qualitative synthesis on transfer processes in psychosocial interventions, from the interventional context to everyday life in the community (paper 2)

3. A randomized control trial to evaluate the effectiveness of MA&R (paper 3 and paper 4)

4. A qualitative study of participants` experiences of occupational engagement in relation to MA&R (paper 5)

For policy makers, professionals, and recipients of mental health services, building a scientific base is pivotal for delivering evidence-based interventions, that are effective, appropriate, acceptable, and implementable. The overall aim with this thesis was to contribute to the scientific field of mental health, namely recovery-oriented practice, by elucidating the question:

"How can occupational therapists and peer-workers employed in mental health services, jointly support people with psychiatric disabilities in engaging in occupations that are meaningful to them?"

Before moving on to the introduction chapter, I want by share an excerpt from a TED talk, which I find captures my motivation for conducting the research on occupations presented in this thesis.

In a TED talk from 2012, *A tale of mental illness – from the inside*, Professor Elyn Saks recalls a question that was posed by a friend: "If there was a pill that would instantly cure you, would you take it?" Prof. Saks, who wrote about her experiences of living with schizophrenia in the book, *The Center Cannot Hold*, responses to this question, by touching upon the poet Rainer Maria Rilke, who was offered psychotherapy and declined, claiming that therapy would not only make his daemons go away, but his angels too. In the TED talk, Prof. Saks says: *"My psychosis (…) is a waking nightmare in which my daemons are so terrifying that all my angels have fled. So, would I take the pill? In an instant. That said, I don`t wish to be seen regretting the life I could have lived, have I had not been mentally ill, nor I am asking anyone for their pity. What I rather wish to say, is that the humanity we all share is more important that the mental illness we may not. What those of us who suffer from mental illness want is what everyone wants: in the words of Sigmund Freud: to work and to love".* (2)

List of abbreviations

BEL:	Balancing Everyday Life
CHIME:	Connectedness, Hope, Identity, Meaning, Empowerment
CONSORT:	Consolidated Standards of Reporting Trials
F-ACT:	Flexible Assertive Community Treatment
GN:	Gør noget – få det godt med psykisk sårbarhed
IMR:	Illness Management and Recovery
IPS:	Individual Placement and Support
LTAD:	Lær at takle angst og depression
MA&R:	Meaningful Activities and Recovery
MRC:	Medical Research Council
OCEBM:	Oxford Center for Evidence Based Medicine
PEO:	Person Environment Occupation
RCT:	Randomized controlled trial
RG:	Resource Groups
SAP:	Statistical Analysis Plan
SE:	Supported Employment
SST:	Social skills training
STC:	Systematic Text Condensation
TIDieR:	Template for Intervention Description and Replication
WHO:	World Health Organization

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1. Introduction

This thesis concerns the development and evaluation of a peer co-led occupational therapy intervention, called Meaningful Activities and Recovery (MA&R), to enable occupational engagement among people with psychiatric disabilities. This chapter outlines the targeted health problem, namely psychiatric disabilities, and their consequences for people's lives. Then follows a description of the service gap that this thesis seeks to address, especially the paucity of evidence-based interventions in mental health services, to support people with psychiatric disabilities in engaging in the everyday activities that matter to them. An occupational perspective of health is introduced, describing the rationale of supporting people who are inhibited from participating the everyday activities, in re-engaging in those. Next, the role of and evidence for occupational therapy in mental health is presented, along with arguments for why the development and evaluation of MA&R was warranted. Finally, research aims are stated.

The overall topic in this thesis is mental illness, which covers a wide range of health conditions, affecting a person`s thinking, moods and behaviors. (3) Globally, an increasing number of people is struggling with mental illness (4), and it is estimated that approximately one-third of the Danish population will during their lifespan receive treatment for a psychiatric disorder. (5) Mental illness is among the leading causes of disability worldwide, with no signs of reduction of burden, so far. (4,6) Psychiatric disabilities mean that the diagnosed mental health condition (e.g., schizophrenia) and environmental obstacles (e.g. lack of support) inhibit the person in performing everyday activities and participating in major life areas, such as work and relationships. (7,8) Psychiatric disabilities have severe consequences for the individual and for the society. People with mental illness, both common mental disorders and severe mental illness, have greater risk of educational discontinuation and for unemployment (9–11), leading to loss of productivity, and threatens financial security and structure in daily life. Furthermore, people living with mental illness often face negative attitudes, prejudices and avoidance due to stigma towards mental illness, which add a substantial burden to the hardship imposed by the mental illness symptoms. (12,13) As a consequence, many are isolated and excluded from becoming valued members of the society. Hence, the effects of mental illness are intrusive, often devastating, on people`s lives, their social statuses and identities. (12,14,15) Qualitative research with people living with mental illness (14,16–18) and time use studies (19–24) have depicted how these effects impact everyday life. For instance, daily life and rhythm can be perceived as fragmented (16), dull or monotonous (17,18). Time use surveys show that people with mental illness spend more time alone, on "doing nothing", and on "quiet" activities such as sleeping, resting, and watching TV, compared to their counterparts without mental illness, from the general population. (20,21,23,24) A British time use study from 2016, reported that not only did the participants spend less time in so-called functional activities (e.g., work or household), they also spend less time on activities that make life enjoyable (e.g., leisure, hanging out with friends, travelling). (20)

The above descriptions of everyday life, is probably familiar to most people who have experiences with mental illness, including people with lived experiences and health care providers. Considering everyday life is not a new approach in mental health, it goes back to the moral treatment area, (25,26) which will be described, later in this chapter. The notion of everyday life taps into at least two conceptualizations of recovery, the overall goal of mental health services. One, clinical recovery, in terms of functioning, which according to the World Health Organization, (WHO) is an umbrella term for health, activity and participation (7), and two, personal recovery, which refers to the person`s unique process of living a meaningful and satisfying life, with or without the presence of mental health problems. (27) The latter, personal recovery which originates from the service-user movement, challenged the mental health services` traditional illness dominated approach to recovery, has influenced the perspectives in mental health services, during the last decades. (27,28) A widely cited definition of personal recovery was proposed in 1993, by Professor Anthony Williams as *"a deeply personal, unique process of changing one's attitudes, values, feelings, goals, skills, and/or roles. It is a way of living a satisfying, hopeful and contributing life, even within the limitations caused by illness."*(29) This definition stressed that recovery is not only about reducing signs of illness (e.g. symptoms and impairments) but placed focus on the personal experiences of recovery, and that recovery involves human growth and personal development. However, this stance was also criticized for putting too much emphasis on the individual aspects, neglecting that recovery is not only an introspective process that encompasses personal growth, but also is a social process that takes place in interpersonal relationships, in a material world and in the community. (30–32) Consequently, supporting people in re-building everyday life is a bedrock in recovery-oriented practice, for instance by strengthening relationships and connectedness to professionals, relatives, friends and community, enhancing hope and resilience, and focusing on human rights, living conditions and inclusion. (31,33–36) Recovery-oriented practice goes beyond psychopathology and acknowledges the impact of trauma, stigma, and societal challenges as barriers to recovery. It has led to a shift in approaches where not only professionalism provided by clinicians such as nurses or occupational therapists, but also experiential knowledge and shared experiences, offered in peer-support, are essential for recovery-oriented services. (31,37) Despite these important evolvements in recovery paradigms in the mental health sector, mental health professionals have in some studies been criticized for mainly being occupied with the symptoms and dysfunctions accompanying mental illness, overlooking people`s opportunities (or lack of same), their knowledge and skills, material resources, their preferences, roles and social status, which allows for engagement and for taking on responsibility. (27,28,33,38) Recently, a critical discourse analysis conducted in a Danish study of mental health professionals employed in various settings, found that although recovery was spoken about as a positive phenomenon, it was also guided by paternalistic power structures where the understanding and resolving of patients` problems were based on biomedical knowledge or on legislations, and the patients remained as patients and the professionals remained as experts. (39,40)

Within psychosocial interventions research, the supported employment model, Individual Placement and Support (IPS) and Social Skills Training (SST) are probably the most investigated approaches. (41–48) Especially IPS has in several Randomized Controlled Trials (RCTs) and meta-analysis demonstrated its effectiveness in assisting people with psychiatric disabilities obtain competitive work or education. (46–48) These evidence-based interventions are significant contributors in the mental health services, as employment and education inarguably are important recovery goals. However, employment and education may not be the only area of daily life that matters to an individual with a psychiatric disability. People are also concerned with having healthy routines, learning new things, enjoying art, culture, and food, taking care of one`s home and loved ones, being a part of the community and so on. Accordingly, there is a need to develop interventions that enable participation in a broader sense of everyday life (independent living, leisure, community activities etc.).

An RCT from 2018, conducted in early intervention services for people with first episode psychosis found that assertive outreach combined with cognitive behavioral therapy could increase time spent on structured activities, with eight hours pr. week, and the effects sustained at six months follow up. (49) Findings from this study are promising and suggest that there is potential for developing practices for community participation in other settings too. Consequently, there is a need for interventions in mental health services, to support people with psychiatric disability in re-claiming an everyday life with activities and routines, that the person finds meaningful and satisfying. Services that go beyond psychopathology and biomedical deficits, where people with psychiatric disabilities are supported and valued for being themselves, for holding on to their hopes and aspirations, and for services that can create accesses and opportunities to participate in everyday activities in the community and in civic life. Or to put it more simply, using Prof. Saks' words: "*What everyone wants: To work and to love."*(2)

1.1. An occupational perspective on health

MA&R is rooted in an occupational perspective on health, stating that a connection exits, between occupation and health, and that opportunities for everyday activities need to be provided. This perspective informs occupational therapists in mental health, working with individuals who due to illness, trauma, social or environmental circumstances are inhibited from engaging in occupations that are meaningful to them. Occupational therapists acknowledge that people`s daily activities, what they spend their time on, where they are and whom they are with, matter for their health and recovery. Therefore, establishing individuals` goals, needs, understanding their actual doing, and how they occupy time and space, while taking the environmental context into account, is essential for occupational therapy practice.

In this context, the term *occupation*[2], refers to everyday activities, not merely a job or a profession, as the word occupation often involves, in common English language. Occupation covers "anything a person does"(50), and is a simple, yet at the same time compounded construct. Being familiar with what occupational therapists mean when applying the terms occupation and occupational engagement, is important for understanding the occupation-health paradigm, and for understanding why occupational engagement was chosen to be the main target for MA&R. Thus, important characteristics of the constructs will be outlined, in the follow paragraph before returning to the occupational perspective on health and how it applies to people with psychiatric disabilities.

1.1.1 A conceptual framework of occupation and occupational engagement.

Occupations are culturally recognizable, continuous activities, that have a purpose. (51) Besides being goal directed, occupations are embedded in the social, cultural, and physical world, and in the stream of time.(52) This feature is important, as an occupation is not solely about "doing", but doing for a reason, that is part of a bigger picture. (53) Everyday life can be apprehended in the temporal lens on occupations, by not only focusing on the type of occupation (e.g., work, rest, leisure) but also by recognizing the duration, frequency, order, and repetition of occupations, and how this reflects people`s time use, habits, routines, and lifestyles. (53)

Occupational engagement is the person`s active involvement in occupations and the result of dynamic transactions between the person, the occupation, and the environment. (54) Occupational engagement differ from occupations, by going beyond the "common understanding" of occupations. Occupations are culturally familiar (a part of the working language in the culture), and there is to some degree consensus on actions and behaviors defining the occupation, (e.g., rules for playing football), and how the occupation is commonly valued in the culture (e.g., paid work, childcare, etc.). (53) Occupational engagement, on the other hand, taps into the person`s subjective experience of the occupation and underlines that doing the observable same thing (e.g. preparing food), can have different meanings to the individual, depending on a wide range of personal factors, such as social roles, identities, age, interest, values, previous experiences and so on. (52,55,56) Hence, occupational engagement encompasses the individuals` active doing (performance) and the reflections and meaning making of their experiences. (19,54,57) Life changing events, such as illness or injuries can alter the meaning individuals attach to their occupations, as shown in research by Hammel. For instance a trivial task, such as putting socks on, can during the rehabilitation process, after a spinal cord injury, become an experience of mastery and independence. (56)

The person-occupation-environment (PEO) model proposes that personal components (physical, psychological and cognitive) influence the person`s ability to engage in occupations. (55) For instance,

[2] In English occupational therapy literature, distinctions are made between activity and occupation. In Scandinavian occupational therapy literature, this distinction is not clear as the word "aktivitet" is used for both activities and occupations.

neuro cognitive difficulties have been associated with psychiatric disabilities, for individuals living with various mental health conditions, such as bipolar disorder, depression and schizophrenia.(58–60) Occupational engagement is not only influenced by personal factors alone, but also the social and material environment the person interacts in. (54) Money, buildings, nature, infrastructure, neighborhoods, people, artifacts, laws and legislations, social norms, and communities, among other things situated in the social, material, and cultural world, all impact what people do, how and with whom they spend their time, and how they move around. (50,52,53,55) For example, private housings can provide opportunities for developing one own`s daily rhythm, while sports clubs can support daily structure through offering regular events.(61) Morris et al, described occupational engagement as a dynamic and fluctuating state, influenced by complex, interacting factors within and outside the person. Occupational engagement can be pictured as a loop, where individuals` participation in occupations changes over time, in response to how they experience the positive and negative consequences of their involvement, and the feedback they get, from the social, cultural, and material environments. (62) This "loop", the individual`s interpretation of doing, and the feedback from the environment is essential for understanding the health-occupation relationship. According to Morris et al, wellbeing occurs when people participate in occupations with perceived positive values and consequences for the individual and the society they live.(62) Occupational engagement can be understood as a helix, where responses (from the person and/or the environment) to occupational engagement foster increased occupational engagement and wellbeing and so forth. How occupational engagement, health and wellbeing are intertwined and how this relate to mental health and recovery will be elaborated on in the following section.

1.1.2 Occupational engagement and recovery

Now, returning the occupation-health paradigm, stating that people`s *engagement in occupations* is pivotal for their health and wellbeing.(50,63) Health is, according to the WHO`s definition, *a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity.* (64) Occupation is viewed as an enabler of health, but it has also been argued that occupation is an aspect of health, suggesting that the occupation-health relationship is inseparable. Dr. Ann Wilcock stated that human beings are occupational beings, that we prompt the "doing of something" to overcome physiological, psychological, or social discomfort, e.g., pain, boredom, hunger, loneliness and more, to maintain functioning of our organism. Thus, occupation is not only an enabler of, or an aspect of health, it is essential for survival and for fulfillment of human needs. (63,65,66) To clarify this complex interrelationship of occupation and health, Dr. Wilcock, proposed that occupations could be understood as a synthesis of *doing, being, becoming and belonging. Doing* refers to a person's overtly (visibly) or tacitly (mentally) engagement in activities. *Being* is introspective and reflective, it refers to a person`s consciousness, creativity, social roles, and the person`s exercise of choice and agency. *Becoming* refers to the process of growth, development, and change. *Becoming* can be initiated through necessity or choice and is directed by goals and aspirations. *Belonging* refers to connectedness to people, places, and communities, and relationships based on reciprocity, mutuality, affirmation, and human worth.(66–68) These fours dimensions, provides a holistic approach for conceptualizing health, much in line with the WHO definition, highlighting both physical, mental and social wellbeing.(67)

The relevance of applying an occupational perspective, in mental health, is two folded.

One, mental illness symptoms, and the social consequences attached to mental health conditions (e.g., prejudices towards people with mental illness) can negatively affect individual`s engagement in meaningful occupations, that is crucial for health, wellbeing and ultimately survival. In other words, when people's occupational engagement is disturbed, their health is threatened. *Occupational dysfunction* is a state caused by illness, life transitions and factors that stand outside the control of the individual, where the person`s usual patterns of occupations are disrupted, a state that can be perceived as a "life in trouble". Occupational dysfunction is entangled within a complexity of factors, it affects health and wellbeing negatively, and it has severe human consequences: loss of meaning, boredom, emptiness, loneliness, maladaptive responses, diminished self-efficacy believes, poverty and marginalization.(69)

Two, occupational engagement is not only related to health and wellbeing, but also linked to recovery. This means that for people with psychiatric disabilities, engaging in activities that are meaningful can be an important part of the recovery process. Being deeply occupied, for instance while watching a thrilling movie, or having a heart-to-heart talk with a friend, can be a relief from worries and everyday hassles and make up small "oasis" or "breathing spaces". Doing things that matters, that one finds important, interesting, or enjoyable, can be a re-connection to interests, values, aspirations, and identities, confirming that one is much more than a service user or a patient. Doing *something* adds structure and content to the day, a sense of accomplishment and a movement to overcome inertia. Thus, becoming re-engaged in occupations, during recovery, can initiate a positive feedback loop and facilitate a health promoting process, a helix in which human can develop.

Occupational engagement encompasses the person`s active doing and holds opportunities for making connections to people and communities, for becoming aware of and developing one`s capacities and identities, for expressing one`s creativity, uniqueness, and aspirations, for experiencing immersion in the activity and a state of flow. All these processes necessitate the synthesis of doing, being, becoming and belonging, as described above (68) These four dimensions in the health-occupation relationship: doing, being, becoming and belonging, holds similarities to central components in personal recovery, for instance, the description of recovery as an active, unique process, the emphasis on recovery as an contextual process embedded in social interactions, and in the persons cultural, material and social environments, as well as the five key recovery processes identified in the CHIME acronym: Connectedness and belonging, Hope and future optimism, Identity and overcoming of stigma, Meaning in life and Empowerment. (70) A scoping review from 2015, explored how recovery and occupational engagement were interlinked. 17 studies, mainly qualitative, were included. Recovery was described as three interrelated, complex, and non-linear occupational processes; 1) gradual re-engagement – doing to get started, 2) engaging within the stream of everyday life, and 3) recovery as full community participation and citizenship. Engaging in small, simple, and non-demanding tasks without pre-planned outcomes or social expectations were perceived as part of recovery as gradual occupational re-engagement. It provided distractions from struggles and allowed individuals to accept illness as part of themselves. Occupational re-engagement, doing "something" instead of nothing, became an anchor to connect with and a way out of a downward spiral of inertia. Small tasks helped to rediscover hope and constructively re-praise capabilities and resources. Recovery was experienced through engagement in ordinary everyday occupations, including routines, doing ordinary things, having "normal" roles and responsibilities, and work. Everyday occupations provided structure and facilitated dealing with challenges, developing a sense of self as capable and normal, rebuilding hope, and connecting to community life. Finally, recovery was experienced as full community participation and citizenship, being immersed in activities well matched with personal and community demands, which linked the individual and the community in socially valued ways. This also meant having opportunities to "give back" and share one`s lived experiences of challenges. Engaging in personally meaningful and socially respected activities and roles promoted a sense of attachment and belonging to the community and fostered growth and personal development. Occupational engagement, the authors concluded, is not merely related to recovery, they *"speak the same language".* (71) Cross sectional studies investigating the relationship between occupational engagement, health and wellbeing, among people with mental illness, have found that occupational engagement is associated with fewer psychiatric symptoms and better self-rated quality of life (24,72) with greater satisfaction with one's social situation, particularly with friendships (73), with self-rated health and functioning (74) and with empowerment.(75) In a sample of 276 services users from a Swedish trial, occupational engagement was, together with mastery, the strongest mediator for change in recovery over a six months' time period.(76) Qualitative studies have found that occupational engagement changes over time, and in accordance with illness episodes and recovery (77), that affirmation, sense of belonging and acceptance is a major source for perceived meaning in occupational engagement (78) and that occupational engagement can be compared to a "life long journey" of learning to live well with one's illness. (79)

1.2. Occupational therapy in mental health

In this section, the historical development of how occupational therapists in mental health work with people with psychiatric disabilities to enable occupational engagement and support recovery in the context in everyday life is outlined. Of importance, is the recent introduction of a new kind of colleague in mental health services, the peer-worker, and how this holds an unrealized potential for promising and fruitful collaborations between occupational therapists and peer-workers with the aim of enabling occupational engagement. Then, the evidence base to inform occupational therapy practice in mental health is summarized, which established a paucity of research available, and led to the development and evaluation of MA&R.

The birth of occupational therapy in mental health cannot be separated from the history of psychiatry, starting with the Enlightenment and the *moral treatment area* (about 1850 to 1920). In opposite to former practices, e.g. madhouses and prisonlike accommodations, moral treatment was based on the premise that people with mental illness deserved to be cared for and treated with respect and dignity. (25) The asylums were established in this period. The word asylum originates from the Greek word *asylon* which means place of refuge or sanctuary. The development of therapeutic communities and healing environments, with emphasis on social relationships and everyday practices, together with the recognition that structured activities had therapeutic value was imperative in this period. Most asylums were in a far distance from towns and cities, in rural surroundings. Staff often lived close to the asylums facilities and became a natural part of everyday life together with the patients. (26,80). Occupational therapy grew out of this premise, that purposeful occupations, everyday relationships and social and physical environments were important resources in helping individuals in recovering their mental health.(26) Occupations, at this point, were mainly considered as gardening, art, craft and other structured activities located within the asylum facilities, with little attention paid to daily life outside the asylums. (25) The moral treatment area and long-time hospitalizations were gradually replaced by the deinstitutionalization reform. The process was driven from an increasing criticism of the asylums of being overcrowded, suppressive and isolating, along with advancements of medical and psychosocial treatment methods. (81) In Denmark, the process was initiated in the late 70`es, replacing long stay psychiatric hospitals with community-based treatment. Over a time span of 20 years, the number of psychiatric hospital beds was reduced from 12700 to about 4200. (82) Psychiatric treatment and care were organized into inpatient units, outpatient clinics, outreach services and specialized treatment. The goal was to support people with mental illness in maintaining life as normal as possible, and to provide differential treatment, prevent hospitalizations and re-hospitalizations, and support community integration. (82,83) The development necessitated mental health professionals to refocus their assessments and approaches from the institutional context, and match the patients` abilities and disabilities against the challenges of adaption in “the real world”. (80) Accordingly, a new type of mental health professional grew out of the deinstitutionalization area – the case manager. The case-manager`s role was to ensure that patients in the community mental health center received the services needed for community integration, primary through creating links between patients and appropriate services. The case-managers were organized in multidisciplinary teams of nurses, psychologists, psychiatrists, social workers and physio- and occupational therapists.(82,83) Consequently, occupational therapists` role in mental health shifted from being facilitators of recreations, arts and crafts activities, to becoming evaluators, trainers and supporters, targeting functioning and everyday living in the community. (84) Rehabilitation models were introduced (83,84), with the goal to enhance levels of functioning and support independent living with the least amount of professional intervention possible.(80,85) Informed by the stress-vulnerability model (86), skills building was seen as fundamental for restoring functioning, and for improving the individuals opportunities for living meaningful, independent lives in the community. (43,80,83) Together with colleagues, for instance nurses and social workers, occupational therapists delivered psychosocial interventions like SST, Illness Management and Recovery (IMR) or Independent Skills Training. (41,87,88) The establishment of community mental health centers, meant that occupational therapists were no longer integrated in the environment and the everyday life of the people they supported, as in the asylum period, and this imposed challenges in the occupational therapy practices with enablement of occupational engagement. From directly engaging people in activities (e.g., by facilitating arts and crafts activities in hospital settings), occupational therapists had to enable engagement, "from a distance", e.g., in their offices in the community mental health centers, or occasionally on home visits. This led to a shift in strategies, towards "talking" techniques such as home assignments, coaching, consulting, education and time use planning.(52,89) Not much research has been conducted, regarding the effectiveness of these strategies, to what extent they actually are useful for enabling participation in activities in the community, but it is reasonable to assume, that they do not benefit everybody and that there are people with psychiatric disabilities for whom more hands-on support or direct engagement (e.g. through companionship) would be helpful.

As a result of the impact from service-users movements, personal accounts, qualitive and quantitative studies, (28,29,36,70,90–94) the recovery paradigm evolved and became mental health policy worldwide. (27,30,95) Accordingly, peer-to peer interventions have gained increasing momentum in Danish mental health services. This development is not unique to Denmark, peer-support has been acknowledged and implemented worldwide, as a cornerstone in recovery-oriented practices. (96,97) Peer-support refers to the process of people sharing their experiences and knowledge to help each other. Peer-support can either take place informally (e.g., between group members at an IMR session) or formally, delivered by peer-workers, in groups or one-on one. Gillard and colleagues have described peer-workers as: "*people with personal experiences of mental health problems employed to use those experiences in supporting others*"(98) In a change model, developed on the basis of multiple interviews with peer-workers, mental health professionals and recipients of peer-support, Gillard et al propose that establishing trusting relationships based on shared experiences, role modelling recovery by showing one can live well with mental illness, and engaging people with mental health services and with the community are major change mechanisms in peer-support offered by peer-workers. (98) Systematic reviews of RCTs investigating peer-support interventions have demonstrated their effectiveness, on outcomes related to recovery, such as increased hope and empowerment. (99–101) Peer-workers` approach is different from occupational therapists`, as peer-workers share personal experiences, highlight reciprocity and mutual help, and draw on experiential knowledge. However, peer-workers and occupational therapists share common visions, supporting people in re-claiming meaningful and satisfying lives in the communities they are parts of. Both occupational therapist and peer-workers center their practices around the needs and priorities, most important to the person they help, and build upon the person`s uniqueness, strengths, and talents. Furthermore, peer-workers and occupational therapists highlight the collaboration and partnership with the person they support, where the person`s own efforts, active involvement and ownership constitute the basic foundation. (97,99) In a systematic review from 2022, Prieto and colleagues, investigated interventions delivered by peer-workers, and identified the outcomes in terms of their relevance for occupational therapy practice. Peer-support interventions were found effective in seven of the ten included studies, e.g., on satisfaction with services, activities on daily living and quality of life. (102) The findings add to the growing evidence base of peer-support, that peer-workers can offer important support to people in their recovery, including in areas concerning occupational engagement. Accordingly, collaborations with peer-workers hold promising opportunities for occupational therapist working in mental health.

Next, the available evidence for occupational therapy in mental health is reviewed. Evidence-based practice includes interventions that in rigorous research are found effective for people who utilizes occupational therapy services in mental health and can inform and guide occupational therapists in delivering high quality recovery-oriented services. In this context, systematic reviews may play a vital role in guiding evidence-based practice but can also provide an overview of existing evidence in the field. A systematic review from 2011, included 52 studies evaluating the effectiveness of occupational therapy interventions focusing on recovery in the areas of community integration and normative life roles, mainly on effectiveness of skills training. After ranking the studies on a grading system based on level I-V from evidence based medicine (103), the authors concluded that there was strong to moderate evidence on social skills training and moderate evidence on neurocognitive training and living skills training, but limited evidence on client centered interventions, and interventions delivered in real life contexts (e.g. in people homes or communities). (104) Same year, a systematic review on occupational therapy interventions for education and employment, for people with mental illness included 46 studies, and found strong evidence for supported employment and education models, such as IPS. (105) In 2017, a meta-analysis estimating the overall effect of occupational therapy interventions on improving occupational performance and well-being among individuals with mental illness, included data from 520 participants in a total of 11 studies. Limited information was provided in studies, about the intervention's contents or conceptual frameworks. The results indicated that occupational therapy interventions had a medium effect on occupational performance and a small effect on wellbeing. The authors stated that more research should be conducted to confirm these findings, and future interventions should be developed with a consistently and clearly described theoretical basis and reported with sufficient details about the intervention. (106) In 2019, a literature review mapped occupational therapy interventions into the following categories: employment and education; psychoeducation; creative occupation or activities, time use and occupational balance; skills and habit development; group or family approaches; and animal-assisted therapy. The interventions were investigated in studies with a broad range of research designs, including RCTs, pre-post intervention designs, qualitative studies, or mixed method designs. The review revealed an expansion of occupational therapy interventions. The number of studies reporting and evaluating occupational therapy interventions was increasing, however the variety of methodology and outcomes reported in the included papers made comparisons difficult, and the evidence base for informing occupational therapy practice in mental health was considered to be scarce. (107) A scoping review from 2019 identified, presented, and assessed studies investigating the effectiveness of occupational therapy interventions in mental health. Four systematic reviews and 21 original studies were included. The results indicated that individualized occupational therapy showed promising effects on cognition and social functioning, while effectiveness on occupational engagement were found in a time use intervention and, in a group-based lifestyle intervention. Many of the included studies had several methodological limitations (e.g., small sample size, lack of power calculation or control group) which compromised the research base to inform occupational therapy practice in mental health, and the authors concluded that more high quality research was needed. (108) A scoping review, from 2021, included 35 studies in English and Spanish language. The aim was to identify occupational therapy interventions and to provide a detailed summary of them. Psychosocial intervention was the most used occupational therapy intervention, followed by psychoeducational and cognitive interventions. The included studies were not assessed for bias or levels of evidence, however the authors pointed out that several had methodological limitations such as small sample sizes and lack of randomization. (109)

2. Rationale

An increasing number of people are struggling with psychiatric disabilities, often with severe and devasting consequences for their lives. Recovery-orientation is mental health policy worldwide and puts emphasis on the individual`s right to live, love and work, to participate in activities that matter to them, in the community. Research has demonstrated the effectiveness of interventions targeting employment and education, but the evidence base to inform health professionals about services to support participation in activities in the broader aspect of everyday life, is scarce.

The development and evaluation of MA&R was based on this gap in current mental health services, namely the lack of evidence-based interventions to support individuals with psychiatric disabilities in engaging in occupations they find meaningful, in the context of their own environments, for instance their homes or in the community. Guiding visions for recovery-oriented practice fit well with occupational therapists' perspectives on health, both paradigms share similarities and common understandings. Thus, the occupational perspective on health, wellbeing and recovery provided the rationale and conceptual framework, for the development of MA&R. Peer-workers are new allies in recovery-oriented mental health and introduce promising opportunities for collaborations with occupational therapists, suggesting that there is a potential in co-developing services and thereby strengthen the mental health practices to successfully enable occupational engagement. None of the interventions identified in the systematic reviews above included co-productions between occupational therapists and peer-workers, so this was an important target for the development of MA&R.

An important aspect to address in the development of MA&R, is a challenging condition for enabling occupational engagement, namely that occupational therapy interventions often are situated in and delivered as office-based services or occasional home visits, which might be insufficient in some cases. Some persons with psychiatric disabilities may not necessarily benefit solely from the “talking techniques”, and need complemental support, e.g., practical help or by doing things together, to engage in the activities they want or need to, in their homes or in their communities. If and how mental health services delivered in institutional settings can transfer between contexts and be helpful in everyday life situations in the community, needed to be addressed, as knowledge on the matter is scarce. Finally, the systematic reviews above found that the evidence base informing occupational therapy in mental health is expanding, but is still limited, and especially studies based on partnerships with peer-workers, studies with stringent and transparent intervention descriptions, studies investigating effectiveness of occupational therapy interventions delivered in “real life” settings and high quality RCTs are warranted.

This thesis contributes to the scientific field in mental health, as it describes the development and evaluation of Meaningful Activities and Recovery (MA&R) a peer co-led occupational therapy intervention to enable occupational engagement among people with psychiatric disabilities. The thesis has two specific aims.

<u>Firstly, the thesis describes the development of MA&R. This is addressed in two studies.</u>

1) A scoping review to identify, present and assess research investigating the effectiveness of occupation – and activity based/focused interventions delivered by occupational therapists in mental health between 2003 and 2018. (Paper 1)

2) A qualitative synthesis of interventional studies, to investigate participants` experiences with transfer from interventional contexts to everyday life in the community. (Paper 2)

<u>Secondly, the thesis describes how MA&R was evaluated. This is addressed in two studies.</u>

1) An RCT, comparing the effectiveness of MA&R as an add-on to standard mental health care, with the effectiveness of standard mental health care alone, on occupational engagement, personal recovery, functioning and quality of life. (Paper 3 and 4)

2) A qualitative study investigating participants` experiences of occupational engagement during MA&R. (Paper 5)

All papers are included in Appendix I

3. Methods

This chapter provides an overall overview of the process of developing and evaluating MA&R, with study designs and research methods applied. The overview is presented in relation to Medical Research Council (MRC) Framework for developing and evaluating complex interventions. (110,111) Following the overview, the scientific foundations in this thesis are introduced, before describing the study designs and methods into detail.

3.1. MA&R in relation to the MRC Framework

The process of developing and evaluating MA&R was inspired by the Medical Research Council (MRC) Framework for developing and evaluation complex interventions.(112,113) The MRC Framework was originally published in 2000 (114), and in updated versions as guidance in 2008 (113) and in 2021 (112). MA&R can be mapped as a complex intervention, as it:

- Contains multiple and interacting intervention components.
- Requires various levels of skills, competences, and behaviors of those who delivers and those who receive the intervention.
- Permits levels of flexibility and tailoring the intervention or its components. (112)

According to the MRC Framework, complex health intervention research is conducted in four distinct but iterative main phases; 1) <u>the development/ identification phase</u>, where a new intervention is developed, or an existing intervention is adapted for a new context, based on research evidence and the theory of the problem, 2) <u>the feasibility phase,</u> where the feasibility and acceptability of the intervention and evaluation design is assessed, 3) <u>evaluation</u>, where the intervention is evaluated in the most appropriate methods to address the research questions, taking on a effectiveness, theory based on system based perspective, and 4) <u>implementation</u> which refers to strategies and approaches to maximize the impact and uptake of successfully evaluated health interventions into practice.(112)

The MRC Framework proposes that in each of the phases, the following six questions are considered: "*How does the intervention interact with its context? What is the underpinning program theory? How can diverse stakeholder perspectives be included in the research? What are the key uncertainties? How can the intervention be refined? What are the comparative resource and outcome consequences of the intervention?"*(112)

It is recommended that the questions are revisited before progressing between the main phases. The phases are not necessarily sequential and how the questions are addressed may impact what direction the research process moves between phases, e.g., from feasibility phase to evaluation, but also back to development phase.

The development and evaluation of MA&R underwent three main phases in the MRC Framework, the development, the feasibility, and the evaluation phase. Figure 1 shows an overview of the phases, the research activities, and papers.

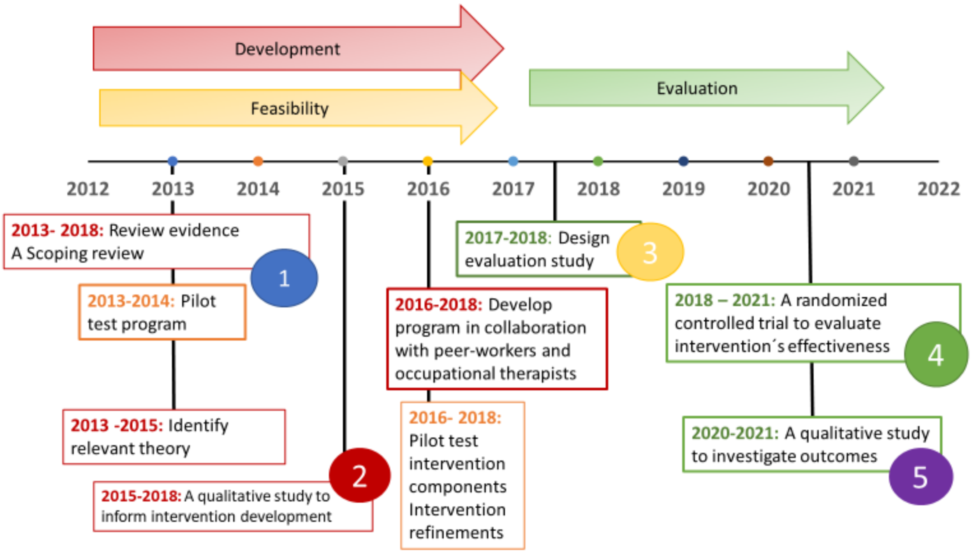


Figure 1: An overview of project timeline (2013-2022), main phases (arrows), research activities (boxes) and papers (circles).

3.1.1 The development of MA&R

The MRC Framework recommends that published research evidence is reviewed before and during the development phase.(112) A scoping review was conducted, to identify and assess studies investigating the effectiveness of occupational therapy interventions in mental health, and published in 2019 (Paper 1). The scoping review did not identify any existing intervention, that had been found effective and was ready to be implemented. Therefore, we focused on an already existing evidence based intervention, developed to another target population, but was about to be adapted to a target population similar to ours. (112) We were introduced to a program called *"Gør noget- få det godt med psykisk sårbarhed"*[3] (GN). The program was developed by two occupational therapists and lectures at the University College of Copenhagen, Christina Jessen -Winge and Lone Decker. It built on principles from the Lifestyle redesign® program, an evidence-based intervention guided by an occupational perspective on health, designed to promote wellbeing and quality of life among elderly. The Lifestyle redesign ® program is described in detail in a later section in this thesis.

I evaluated GN in a pilot study in 2013-2014, regarding the program`s feasibility and acceptance. Results from the study were reported in my master thesis, (115) and showed that both participants and occupational therapists, found GN useful in focusing on personal strengths and resources, and it provided valuable

[3] English translation:" Do something – get better"

information about the health promoting potential of occupations. However, the findings also indicated that the group format did not facilitate occupational engagement. Participants reported that occupations mainly became a subject for group conversations without occupational engagement taking place outside the group setting. We therefore deemed that the intervention should be developed further to enable occupational engagement in the participants` everyday life in the community. In this context, more knowledge was needed, on how occupational engagement in the community could be supported, namely from an institutional context, where mental health services are situated. Following the pilot study, theories on transfer were identified to inform further development and refinement of the intervention. A qualitative study was conducted between 2015 and 2017, to investigate how skills, knowledge and competencies acquired during group based and individual interventions are transferred and utilized in daily life in the community. Findings from this study were published in 2021 (Paper 2). Peer-workers and occupational therapists in community mental health centers were identified as relevant stakeholders in the development phase. Between 2016 and 2018, MA&R was developed and designed in a collaboration with these stakeholders, inspired by the agile development methodology. (116) This means that components in the intervention (themes, contents, and activities) were developed in iterations of designing, testing, review, and adjustment. The MA&R material (manuals, slides, and workbooks to participants) was designed in a close collaboration with a consultant, who had an academic background within communication, and personal experiences with psychotherapeutic group sessions, being a former service user. The process of developing the intervention is briefly reported in the protocol article, published in 2020 (Paper 3)

3.1.2. The feasibility of MA&R

According to the MRC Framework, feasibility studies should be performed to evaluate the feasibility of a) the intervention and b) the evaluation design. Feasibility was investigated in two phases, in the pilot study of GN from 2013 to 2014, and in the development process of MA&R from 2015 to 2018. The pilot study from 2013-2014 applied a qualitative research design to investigate occupational therapists and participants experiences with GN. Participation rate, retention, and recruitment time were also assessed. Some study design methods, such as data collection methods and the outcome measures` sensitivity to measuring change were investigated. The outcome measures (functioning, measured by Personal and Social Performance Scale (117), and quality of life, measured by SF-36 (118)) from the pilot study were not used in the evaluation study, as we identified more appropriate outcome measures during the development of MA&R. In the period of 2015 to 2018, intervention development and feasibility evaluation were conducted as two interrelated and iterative processes, and not as two distinct main phases as depicted in the MRC Framework.

3.1.3 Evaluating the effectiveness and participants perspectives of MA&R

Multiple research perspectives and - designs can be used for the evaluation of complex interventions, e.g. efficacy, effectiveness, theory based or systems. (112) Findings from the scoping review (108) highlighted the need for high quality studies to contribute to the evidence base for occupational therapy interventions in mental health, and to inform occupational therapists in choosing and delivering interventions to enable occupational engagement, therefore, an effectiveness perspective was chosen. An effectiveness perspective, as opposite to an efficacy perspective has the strength of providing information on whether the intervention works in real-world settings. (119,120) As stated in the MRC Framework, the effectiveness perspective was applied to "*identify an unbiased estimate of the average effect of the intervention, in a heterogeneous context that is representative of the scenarios in which the intervention will be applied in practice. In an effectiveness study, the comparison is with 'treatment as usual' or sometimes with an optimized version of treatment as usual."*(112) In order to evaluate the effectiveness of the intervention, a randomized controlled trial (RCT) was designed following the guidelines from the 2010 Consolidated Standards of Reporting Trials (CONSORT) statements for parallel randomized trial. (121) The trial design and methods were reported in a protocol paper published in 2020 (paper 3). The trial was conducted as a multi-center RCT between 2018 and 2021, with community mental health centers and municipally mental health services as partaking sites. Results from this trial are not published yet but reported in a manuscript draft (paper 4).

Applying solely an effectiveness perspective comes with limitations in respect of evaluating complex interventions. (112,122) Given that contextual factors and individual variations affect outcomes, as described earlier, the effectiveness design does not allow to explore intervention mechanisms and how those are influenced in various settings. (122) Contrary to the effectiveness perspective, theory-based perspectives put less emphasis on the average effect estimate and focus on insights into the interplay of mechanism and context, how change is enabled and how this may vary across different contexts and recipients of the intervention. Theory based studies may help interpret findings from clinical trials, revise program theory and anticipated change mechanisms, inform intervention refinement and/or implementation. (112,123,124) Therefore, a qualitative study, in conjunction with the effectiveness evaluation, to examine how participants experienced occupational engagement, during the MA&R intervention was initiated. (paper 5).

The next section introduces the two overall scientific traditions, that the research in this thesis is rooted in: Positivism and critical realism, and the interpretivist and constructivist paradigm. Then, the method chapter is divided into two main sections, covering the two specific aims in this thesis: one, the development of MA&R and two, the evaluation of MA&R. The section concerning the development of MA&R consists of methodological descriptions regarding 1) *the scoping review*, to identify the available research base, 2) a *description of Lifestyle redesign®,* the evidence-based intervention that GN built on, that was adopted to another target population and 3) *the qualitative synthesis*, to explore the process of transfer from institutional settings, to everyday life in the community. Findings from this study informed the development of MA&R from GN into its current format. The section concerning the evaluation of MA&R consist of methodological descriptions regarding 1) the *randomized controlled trial* to investigate the effectiveness of MA&R, and 2) the *qualitative study* to explore participants experience of occupational engagement in relation to MA&R.

3.2. Scientific foundations

According to Lincoln and Guba, a paradigm can be viewed as basic belief systems, representing a worldview. It is based on an ontological, an epistemological and a methodological stance, dealing with what is the form and nature of reality (knowledge), what is the nature of the relationship between the inquirer and knowledge and in what way the inquirer can access knowledge. (125) When applied in health research, paradigms position the researcher in relation to her understanding of knowledge (epistemological standpoint) and of reality (oncological standpoint), as well as what constitute legitimate inquiry (125,126) The development and evaluation of MA&R was embedded in two distinct paradigms, positivism/critical realism and interpretivism/constructivism, both influencing the studies objectives and designs, and consequently, the type of knowledge produced.

The ontology in **positivism** is based on realism, positing that an apprehensible reality exists, with natural laws and mechanisms. Knowledge is in realism, characterized as generalizations, meaning knowledge is independent of time or context, and in some cases, knowledge can be cause- effect laws. In essence, research can converge upon the *"true state of affairs"*, however post positivism, also called critical realism, later challenged this "naïve" realism. **Critical realism** also assumes that a reality exists, but it is only partly apprehensible, because of insufficient human intellectual capacities and the complex and unmanageable nature of the phenomena. (125) Karl Popper (1902-1994) opposed to the classical and inductive positivistic scientific paradigm that was based on knowledge being obtained through methodical scientific observation of reality. Popper argued that it is easy to obtain confirmation and verification for nearly every theory if one looked for confirmation of it. Observations tend to be explained in the light of the theory applied. Popper stated that *"Confirmations should count only if they are the result of risky predictions; that is to say, if, unenlightened by the theory in question, we should have expected an event which was incompatible with the theory — an event which would have refuted the theory."* Good scientific theories are prohibitions, they forbid things to happen. Consequently, a theory that is not refutable by any conceivable event, is non-scientific. According to Popper, *the criterion of the scientific status of a theory is its falsifiability, or refutability, or testability.* (127,128). Central for research, rooted in the positivistic and critical realistic paradigm is that the methodology is experimental and manipulative, that questions and/or hypothesis are stated as proposition forms and subjected to empirical testing to verify and reject them. The research is guided by a dualistic and objectivistic ideal, where the investigator and the investigated are independent entities. Ideally, the investigator must be able to study the objective without influencing it or being influenced by it. Therefore, external regulations must be undertaken to enhance objectivity, and possible confounding factors must be controlled from preventing outcomes from being improperly influenced. (125)

In the **interpretive** and **constructivist** paradigm, realty is apprehensible as *multiple and intangible mental constructions*, based on experiences and social interactions, they are local and specific in their nature, and depend on the person and/or the group holding the constructions. (125) In short, people construct their realty, by attaching meaning to events and actions. (126) The relationship between the researcher and the object of investigation, is interlinked, meaning that knowledge is not “gathered”, but rather *created* during the research process. Accordingly, knowledge is elicited and refined throughout the interaction between the researcher and the respondents. (125) The field of interest, within this paradigm, is therefore “thick descriptions”, that is descriptions of how events are interpreted to the research subject, how they view what happened to them and around them. The goal of the researcher is to identify and establish patterns and nuances in the meaning that people associate with particular life events.(126) Methodologies within qualitative research consist of systematic collection, organization, and interpretation of texts derived from talk and/or observation. (123) The methodologies explore meanings of social phenomena as experienced by individuals themselves, in their natural context, and therefore applies an interpretive, naturalistic approach to the world.

Hermeneutic phenomenology resolves around the life world of human experience as it is lived and focus on illuminating details and seemingly trivial aspects within experience that may be taken for granted in our lives, with a goal of creating meaning and achieving a sense of understanding. (125,129) Hermeneutic distinct from phenomenology by stating that pre-understanding is a structure and condition for being in the world, and therefore nothing can be encountered without the reference to the researcher’s and the responder`s background understanding. Hence, interpretation is a critical feature in the process of hermeneutic phenomenology. Another one of the most influential philosophers of science, Hans Georg Gadamer (1900-2002) proposes that science is a melt of two separate understandings, the researcher`s and the object of research`s. Those two`s understandings creates a new understanding, *a fusion of horizons, a dialectical interaction between the expectation of the interpreter and the meaning of the text.*(129) The interpretation, is in the hermeneutic phenomenology an ongoing dialogue between the researcher`s  and the subject`s understanding of the phenomena being investigated.

3.3 Development of MA&R

This section describes the methods undertaken in the development of MA&R: Review of evidence (scoping review), description of the program (Lifestyle redesign®) that was adapted and pilot tested, identification of relevant theory (transfer) and the qualitative study to inform intervention development, as depicted in the four boxes to the left in figure 2.

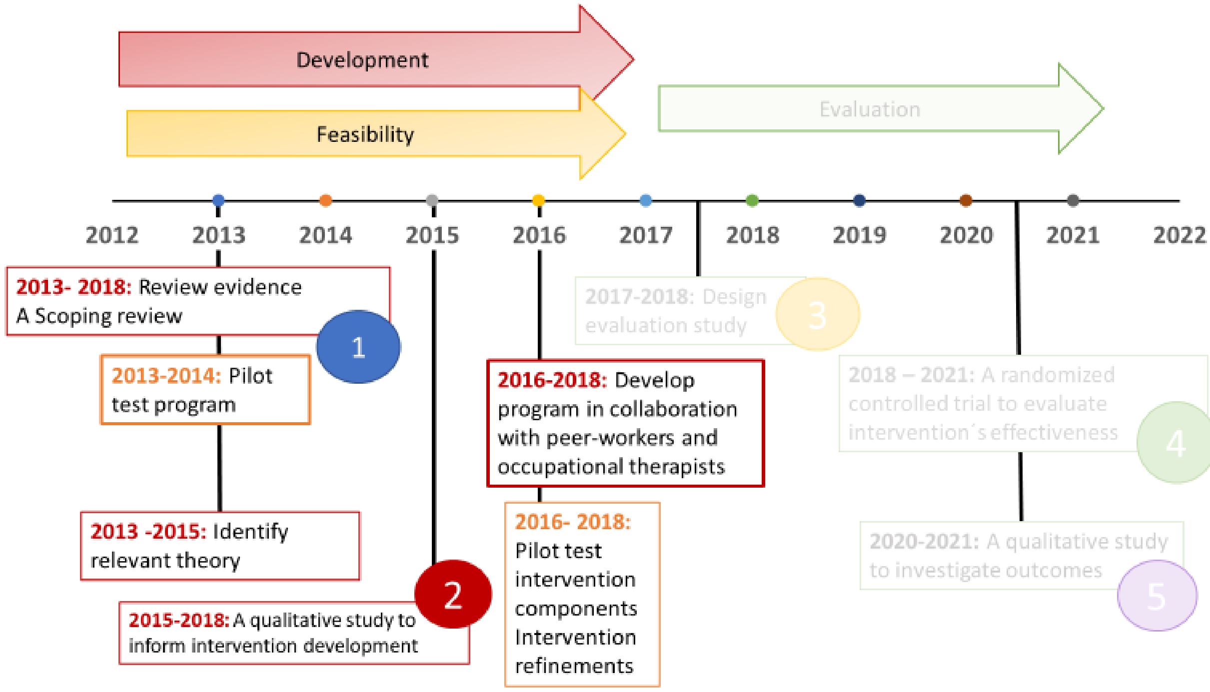


Figure 2: Research activities related to the development (and feasibility) of MA&R.

3.3.1 A scoping review of occupational therapy interventions in mental health

The scoping review methodology was chosen as it was deemed to be more suitable to map the existing research literature in the field, rather than a systematic review design that may be more appropriate when the aim is to provide an answer to a specific clinical question. (130,131) The scoping review followed the five steps as described by Arskey and O`Malley: 1) identifying the research question, 2) identifying relevant studies, 3) study selection, 4) charting the data and 5) Collating, summarizing, and reporting the data. (89). The research question was: "*What is the recent evidence to support occupational therapy interventions in mental health settings*"(108) More specially the review focused on studies that have investigated the effectiveness of occupation-and activity-based/focused interventions performed by occupational therapists in mental health. Six electronic databases were searched: PubMed, Embase, Cinahl, PsychInfo, OT Seeker and Cochrane Library. The PICO model informed the search strategy: Population (P) was defined as people aged 18 years and over, with common or severe mental illnesses. Interventions (I) were defined as occupation- or activity-based and focused interventions, delivered by occupational therapists in mental health. Comparisons (C) of effect, effectiveness, and evidence were chosen as search terms searching for randomized controlled trials, quasi-experimental trials and follow up studies. Outcome (O) was not specified in the search. Search terms were combined with the Boolean operators AND, OR to both broaden and narrow the literature search. Inclusion criteria for selecting studies were original full text articles and reviews, written in English language and published between 2003 and 2018. Randomized controlled trials, quasi-randomized studies, quasi-experimental trials, and follow-up studies were included. In addition to the five steps proposed by Arskey and O`Malley, a critical quality assessment was performed to assess the quality of the studies. When applicable, the Critical Appraisal Skills Program (2018) checklists for randomized controlled trials and for systematic reviews (132) were used to assess the methodological quality of the included reviews and original studies. We used a ranking system, the Oxford Center for Evidence Based Medicine (OCEBM) Levels of Evidence (133) to assess whether there were occupational therapy interventions, that had demonstrated their effectiveness. Consistent with other hierarchal classification systems for evidence, the OCEBM Levels of evidence places randomized control trials on the top of the evidence hierarchy. (133,134)

3.3.2 The Lifestyle Redesign program®

The literature search in the scoping review led to few results, in respect to identifying occupational therapy interventions that were evidence based or co-produced/co-led by occupational therapists and peer-workers. As beforementioned, we decided to develop MA&R from the danish program GN, that was pilot tested in 2013-2014. GN is developed on the principle of the evidence-based intervention, Lifestyle Redesign® and roughly builds on the same format. Since GN and MA&R both relies on these principles, Lifestyle Redesign ® is introduced in this section.

The Lifestyle Redesign ® program was developed in USA, in the1990`s, to enhance health and wellbeing among community dwelling older adults. It is a nine-months long, group-based intervention, led by occupational therapists, with weekly sessions, supplemented with one monthly one-on-one sessions. The program features a process of developing individually tailored plans of lifestyle redesign, in which the participants are encouraged to employ occupations in a personal way to adapt to challenges associated with aging. The program is informed by dynamic system theory, (135) to understand patterns of change and stability in human occupations. It is assumed that the participants, while experiencing age-related decline, have the potential to re-order their patterns of occupations from states of disequilibrium to more stable, complex patterns. According to dynamic system theory, change is neither predetermined or linear, thus the aim of the Lifestyle Redesign ® program is to provide information and occupational experience that will help each participant in understanding their occupations, recognizing the potential for change and identify the multiple factors that would impact lasting change. The participants are taught about the health-related impacts of occupations, e.g., how occupations can contribute to creativity or calmness. Accordingly, they can construct daily routines that promote health and wellbeing, preparing them as “reflective individuals” who, after completing the program, gain greater knowledge and appreciation of occupations, in the context of keeping healthy. Participants are provided with tools to consciously recognize their options, to make health promoting choices and to perceive meaning and satisfaction in their routines. Delivery methods of Lifestyle Redesign® are didactic presentations, peer exchange, direct experiences with occupations and personal explorations. Typically, participants are first educated by the occupational therapist or a guest speaker, and as the session proceed participants share their knowledge and experiences. They practice new themes in their local environment, often as a group outing. Direct experience with occupations is considered a critical component in the Lifestyle Redesign Program, suggesting that personal growth is enhanced by opportunities to embrace self-chosen risks in occupations. (136)

The principles and methods in Lifestyle Redesign ® Program served as the base, that GN was designed upon. GN has a similar format to Lifestyle Redesign ®. Both being group-based interventions, led by occupational therapists, but GN has a shorter duration and lasts about three months.

The Lifestyle Redesign ® program is based on the occupation – health paradigm and emphasizes the individuals` active involvement in his or her life situation and community, the acknowledgement of the participants being experts in their own lives, and the utilization of peer-support. Hence, we found that there was a good fit between the Lifestyle Redesign ® program, recovery-orientation, and occupational therapy practice in mental health, indicating that the program could be suitable and adapted to the target group in this study.

Following the results from the pilot study of GN, we deemed that greater attention needed to be paid, to how occupational engagement beyond the group setting, in the community could be enabled. Therefore, more research was warranted, about potential change mechanisms especially focusing on transfer, to develop the MA&R program.

3.3.3 Identification of theory and a qualitative synthesis of transfer

The rationale for an intervention, and how the changes can be achieved, may be unclear in the outset. Before evaluation can be undertaken, the intervention must be developed to a point, where it can be expected that it has a substantial impact on the intended outcome. (113) A key uncertainty during the development of the MA&R, was how the intervention could impact occupational engagement. The Lifestyle redesign ® program and GN was informed by dynamic system theory and proposed that through provision of information and opportunities for occupational experience, the participants would understand their occupations, recognize the potential and the factors essential for enabling changes. Consequently, this would lead to enhanced physical and mental health, greater life satisfaction and superior occupational functioning. (136) However findings from the pilot study, (115) suggested that information, peer exchange and providing opportunities for engaging in activities by planning home practice in group sessions, did not impact occupational engagement. For instance, some participants did not like home assignments, or forgot them. Consequently, we found that the dynamic system theory approach alone could not underpin potential change mechanisms. As mentioned before, in this phase, identification of theories that can pinpoint potential change mechanisms, is essential for program theory and intervention development/refinement. Thus, following the findings from the pilot study, we deemed that dynamic system theory needed to be complemented with other theories on change mechanisms and that we needed to better understand the process of *transfer*. Transfer is a concept that stems from learning theories and refers to the context of transferring what one has learned in one context to another. (137) We anticipated that a better conception of transfer, could inform intervention development and consequently increase the interventions impact on occupational engagement. Since transfer theories originate from a different context than ours, namely adult education settings or organizational training, (137,138) we wanted to investigate how transfer occurred in psychosocial interventions, targeting people with mental illness, seen from the participants` perspectives.

The study synthesized qualitative research of participants` experiences with different psychosocial interventions. In a synthesis, separate parts are brought together, to construct a "whole", that is greater than the sum of its parts (139), to generate new knowledge on a certain topic. (140) The topic of interest in the study was *transfer.* The objective was to explore participants' experiences with transfer in 1) IMR; and 2) two programs based on peer support: Vendepunkter[4], and Lær at takle angst og depression[5] (LTAD); and whether peer support within these programs influenced the process of transfer beyond the interventional context. Furthermore, participants' experiences with IPS to illuminate whether an intervention delivered in the context of "real world" would eliminate challenges in the transfer process, was also investigated.

The study consisted of semi-structured interviews derived from the abovementioned interventions. A summary of the interventions aims, and theoretical underpinnings are provided in table 1

Intervention	Aim	Theoretical Underpinnings	Brief description of change mechanisms
Illness Management and Recovery (IMR)	To help people with severe mental illness in gaining knowledge and skills to manage their illness and to set and achieve personal goals.	The Stress-vulnerability model The transtheoretical model (Stages of Change model)	Change is enabled by goal setting and by learning skills and strategies (through social skills training, psychoeducation, and cognitive behavioral techniques) to reduce vulnerability and increase functioning. Strategies must be modified according the individual`s stage of change. (87)
1) Vendepunkter 2) LTAD	1) To assist people with mental illness/vulnerabilities in developing skills and strategies to pursue recovery 2) To help people with depression and anxiety to obtain control over the illness and tackle the challenges associated with the illness	Social learning theory, social comparison theory Therapeutic alliance, attachment theory	Building trusting relationships, based on shared lived experiences, leads to role modelling recovery and living well with mental illness, to bridge to mental health services and to engage with wider community. (98)

[4] English: Turning Points
[5] English: Learn how to tackle anxiety and depression

IPS	To help people with severe mental illness to gain competitive employment (or education)	The social model of disability Place-then train model	Societal factors impacting psychiatric disabilities must be addressed. Change is enabled trough modification of the persons real-world environment, (as opposite to institutional settings) and through supporting the person in developing skills and strategies to cope with that environment. (141)

Table 1: An overview of the interventions aims, theories and anticipated mechanisms of change. (142)

The material partly consisted of secondary analyses of existing data sets from two studies investigating participants' experiences with IMR and IPS. (143,144).

The original research aims in the studies on IMR and IPS where our data stemmed from, were

- Did the participants in IMR experience changes, and how did these changes relate to their recovery during or after their participation in IMR? (139)
- How did IPS and employment influence recovery in persons with severe mental illness? (144)

We deemed that the research questions posed in the studies, were compatible with ours, since they explored change processes (in relation to recovery) during the intervention, seen from the participants perspectives. We had ethical concerns around the use of data gathered in personal and trusting relationship between the researcher in the original study, and the respondent. (145) Informed consents from the original studies, in respect to how they stated that data would be used, were scrutinized, and carefully considered whether they corresponded to the aim in the qualitative synthesis. All transcripts were anonymized prior to analysis. I sought to enhance my familiarity with the context in which the original studies were undertaken. I was employed in the same research units as the researchers conducting the studies, which eased the communication about the study`s contexts. I oriented myself about the studies objectives, the sample, how it was recruited in the studies, and the interventions. (145) I performed interviews with persons who participated in one of the two peer-led programs: LTAD or Vendepunkter. I developed a semi-structured interview guide, with questions corresponding to the interview guides from IMR and IPS. (Appendix II) Participants were recruited through the peer-led program coordinators or by the undersigned, visiting one of the group sessions to present the study. A purposeful sampling strategy was deployed (146), aiming for variation in sex, age, and intervention attendance. Unfortunately, participants who had left the program before completing it, did not respond to the invitation. After first recruitment round, most of the participants were female and we decided to recruit a second round, to include more men in the sample. The unified material for this qualitative synthesis comprised a total of 39 interviews. The analysis was guided by the template method as described by Nigel King. (147)

3.4. Evaluation of MA&R

Following the development of MA&R, from 2013 to 2018, the intervention was in 2018 ready to be evaluated in a randomized controlled trial for its effectiveness. In 2020 and 2021, in conjunction to the trial, a qualitative evaluation of MA&R was undertaken (figure 3). This section describes methods used to evaluate MA&R: The design of the RCT and the qualitative study based on semi-structured interviews with participants form MA&R, as depicted in the three boxes in figure 3.

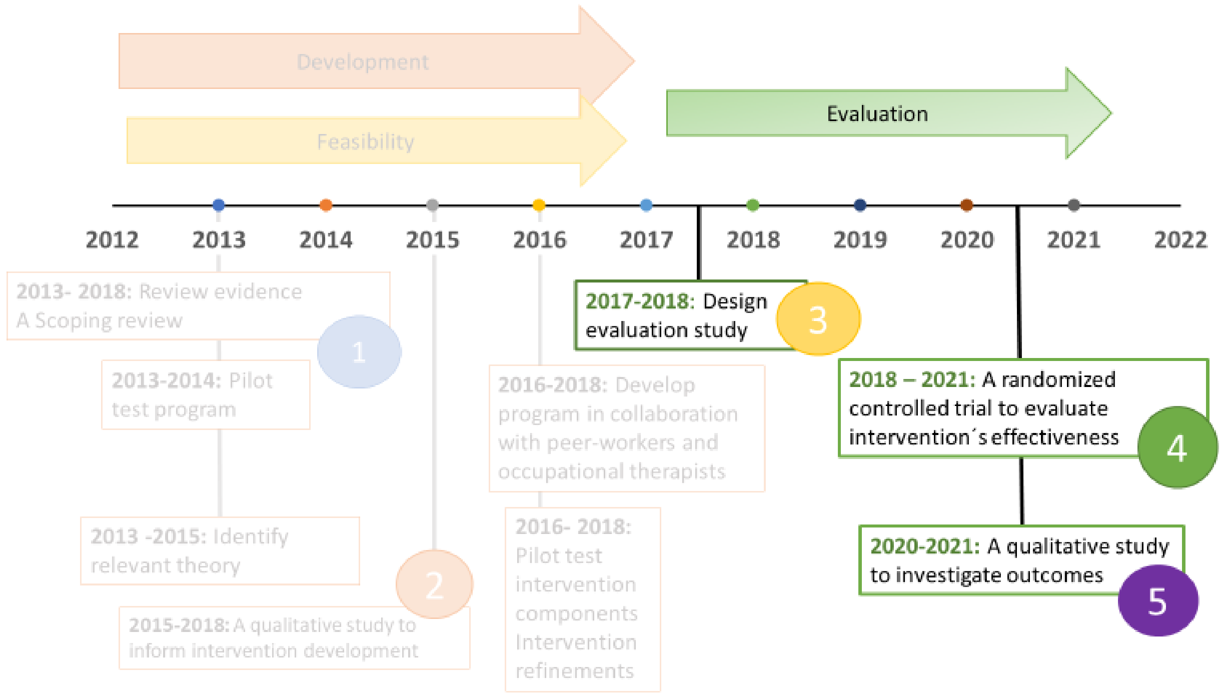


Figure 3: Research activities related to evaluation of MA&R

3.4.1. The randomized controlled trial

Summary of study protocol described in paper 3 (Appendix I).

For determining whether there is a cause- effect relationship between an intervention and its intended outcome, RCTs are viewed as the golden standard. RCTs, when well designed and conducted, contain key features to minimize the risk of systematic errors in the research methodology (bias); confounding factors associated both with the intervention and the outcomes, and the risk of associations between the intervention and the outcome being obtained by random errors, consequently enhancing the validity of the findings. (148) In accordance with Poppers falsification principle, (128) an a priori hypothesis was developed, stipulating the anticipated association between the intervention and the outcome variables, in this study, an association between the MA&R and occupational engagement, recovery, functioning and quality of life, that could be statistical tested. The outcomes were all self-reported and measured with questionnaires, prior to randomization and at post intervention assessments. An overview of the outcomes, questionnaires, and a brief description of them is provided in table 2.

Outcome	Measure	Description	Number of items	Range
Primary outcome				
Occupational engagement	Profiles of Occupational Engagement in people with Severe mental illness-Self-rated version (POES-S). (149)	POES- S assesses time-use patterns of activity performance and the extent to which these patterns are characterized by engagement. The measure consists of two parts: a 24-h, yesterday time-use diary sheet, and a questionnaire with nine items related to occupational engagement. The nine items concern: 1) daily rhythm of activity and rest, 2) moving around in society without hinderance, 3) variety and range of occupations, 4) spending time in a variety of social environments without hinderance, 5) social interplay, 6) making sense of occupational experiences, 7) extent of meaningful occupations, 8) routines and 9) initiating performance. Each item is rated on a scale from 1 to 4. Items are added to a total score, higher values indicate greater occupational engagement.(149)	9	9-36
Secondary outcomes				
Functioning	WHODAS 2.0 12-item version. (150)	WHODAS 2.0 12 item version consists of 12 items derived from the WHODAS 2.0 36-item version, covering six domains of functioning: Cognition, mobility– moving & getting around, self-care, getting along– interacting with other people, life activities– domestic responsibilities, leisure, work & school, and participation– joining in community activities. Each item	12	12-60 (or 0-100, metric range)

		is rated on a scale from 1 to 5. The items can be added together to a sum score or converted into a complex score (using WHODAS software system) on a metric range.(150)		
Personal recovery	Questionnaire about processes of recovery (QPR)(151)	QPR contains 15 items reflecting aspects of the personal recovery process, e.g., relationships, sense of agency and hope. Each item is rated on a scale from 0-4, and added together to a sum score. (151)	15	0-60
Quality of life	Manchester short assessment of quality of life (MANSA)(152)	MANSA contains 16 items related to quality of life, e.g., satisfaction with life, relationships, financial situation, etc. 12 of the items are numerical variables and be rated on a scale from 1-7 and added together to a total score. (152)	16	12-84
Exploratory outcomes				
Functioning	WHODAS 2.0 36 items version (150)	WHODAS 2.0. 36 item version consist of 36 items, covering the forementioned six domains of functioning. Each domain contains between five to eight items, each item is rated on a scale from 1 to 5. The items can be added together to a domain score and a sum score. The sum score can be converted into a complex score (using WHODAS software system) on a metric range. (150)	36	36-180 (or 0-100, metric range)
Health - related quality of life	EuroQol (EQ-5D-3L) (153)	EQ-5D-3L contains five dimensions: mobility, self-care, usual activities, depression/anxiety, and pain. Each combination of answers is converted and provided with a number between 0 and 1. It also entails a visual analogue scale (VAS) on self-rated health (1-100) (153)	5	0-1 (VAS scale 0-100)

Table 2: Overview of primary, secondary, and exploratory outcomes, and questionnaires applied for data collection. (Copied from paper 4)

SAMPLE SIZE: A sample size calculation was performed, to ensure that enough participants were recruited, to detect a difference between the interventions, if it existed. (154) It was performed on the primary objective of the study, to detect a minimal but clinically significant difference between the intervention group and the control group on POES-S (occupational engagement). The clinically significant difference was set to be 3 points on the POES-S scale, corresponding to a moderate effect size. (Cohen`s d= 0,5) (154) This was determined based on Eklund et al. study which found a small effect of 1.4 points measured on POES-S (d = 0.27), on the BEL intervention. (155) We proposed a moderate effect size, since MA&R has a more comprehensive format (in terms of duration and costs) than BEL. Based on the BEL trial, the standard deviation in the study population was anticipated to be 6. To achieve a statistical power of 80% and a significance level of 5%, a total of 128 participants had to be included in the RCT; 64 in each group to detect the difference.(154)

BLINDING AND RANDOMISATION: While designing the RCT, procedures for concealing randomization throughout the study period, minimizing the risk of bias when randomly assigning participants to intervention group or control group were considered. Hence, the allocation sequence was generated by a staff member, not affiliated with the research team, and kept away from the research team, the entire study period. Blocked randomization was used, with block sizes unknown to the research team, to ensure that the number of participants assigned to each group was equally distributed. Randomization was stratified for sex, attempting to minimize the possibility of confounding factors being unequal distributed between intervention group and control group. Significant differences between groups at baseline, were tested, for factors assuming to have a prognostic association with the outcomes, for instance age and baseline values. An intention-to-treat analysis, was planned, so all participants who were randomized, also were analyzed. (148) Intention-to-treat analysis ensures that the prognostic balance, afforded by randomization is preserved throughout the entire study and prevents the risk of comparing groups that differ in respect of prognostic factors, e.g. levels of disability or individuals dropping out of the intervention due to missing effects. (156) The investigator was blinded to group allocation during initial assessment, which took place before randomization, at data collection at follow up, and during analysis, only referring to the intervention group and the control group as group X and Y. However, it was not possible to blind the participants nor the staff for intervention allocation. This may have produced bias, due to the extra attention to and expectations in the intervention group. Introducing an active comparison intervention in the control group, would have reduced this risk of bias. (148). The trial had predominantly a pragmatic approach (119,157–159) as it investigated whether MA&R worked under "real world conditions", as opposite to "ideal conditions" as in trials with a more explanatory approach. (119,160) Broad eligibility criteria were applied, (adults with psychiatric disabilities) where all participants, with few exceptions, who were interested in the study and had the condition of interest, could participate, thus reflecting the intervention`s target group in the real world. The RCT was a multi-center study and MA&R was applied by different occupational therapists and peer-workers in community mental health centers and municipality mental health services, and compared to interventions that were usual practice at the site. (119)

INTERVENTIONS: **MA&R** is an approximately eight-month peer co-led occupational therapy intervention, consisting of 11 group sessions and 11 individual sessions, in addition to individual support, to support occupational engagement and recovery among people with psychiatric disabilities. MA&R is described in detail, in a later section using the Template for intervention description of replication (TIDieR) checklist and guide. (161) **Standard mental health care** was the usual services delivered in the partaking sites. The partaking sites in this study were 3 community mental health centers in Copenhagen, 2 activity and support centers in Copenhagen, 1 activity and support center in Svendborg, and a rehabilitation team in Odense. A brief description of the standard mental health care offered in the sites is provided in table 3.

Recruitment site	Intervention description
[6]Community mental health services (n=3)	• Treatment is delivered according to the F-ACT model • Medical assessments by psychiatrists • Case management, relational support, regular follow up visits • Interdisciplinary treatment, tailored to patient`s needs, for instance: - Peer-support groups - Psychoeducation (individual and/or group) - Physiotherapy - Psychotherapy - Occupational therapy (assessments and/or brief ADL training) - Social counselling - IPS (vocational rehabilitation) - Medicine
[7]Activity and social support centers (n=3)	• Relational support (staff, informal peer-support, peer-workers) • Café • Creative activities • Debate group • NADA • [1]Self-esteem groups • [1]Social skills groups • Sports activities • Social happenings • Healthy lifestyle group • [1]Counselling regarding job opportunities • [1]Internship and voluntary work in kitchen, café, reception, office, and PR
[1]Rehabiltation service team	• Individual and group-based rehabilitation services, for instance - Self-esteem group - Group for people diagnosed with borderline personality disorders - Acceptance and commitment therapy group - Anxiety group - Social skills group - Mindfulness group

[6] Services require visitation

[7] Types of interventions varied between activity and social support centers, except from café, relational support, social happenings, and creative groups, which was offered at all three sites.

Table 3: An overview of interventions offered at the recruitment sites

STATISTICAL ANALYSIS: Prior to the analysis, a statistical analysis plan, (SAP) was developed under close supervision and guidance, from the supervisors and from the co-author from paper 4, Dr. Carsten Hjorthøj (CH). The SAP was developed with inspiration from the guidelines for the content of statistical analysis plans in clinical trials (162) and uploaded at ClinicalTrials.gov. The SAP is found in appendix III. Outcomes in the trials were analyzed according to the intention-to treat principle, meaning that all analysis were based on all included participants in the trial. For baseline variables, the chi^2 test was used to test for differences between the groups in nominal variables (e.g., sex, psychiatric diagnosis) and the t-test was used to test for differences in ordinal/continuous variables (e.g., age, functioning, occupational engagement). At post intervention follow up, differences between the groups were analyzed using ANOVA to determine statistical significance. For missing data at follow up, differences between responders and non-responders were analyzed, and no significant differences between them, in any of the baseline measures were found. Hence, we deemed that data was missing at random and that multiple imputation to address the issue of missing data could be used. (163) Post hoc, two additional analysis to address two questions that were not prespecified in the SAP were performed:

1. To examine whether the two intervention groups (MA&R+ standard mental healthcare and standard mental healthcare alone) demonstrated positive changes from baseline to post intervention follow up assessments. To evaluate these within group changes, post intervention assessments were compared to baseline in the intervention group and the control group, respectively, and paired t-test was used for statistical significance.

2. To examine whether there was a difference in treatment effects, in the MA&R interventions delivered under "normal conditions" and MA&R interventions delivered under conditions being impacted of the COVID 19 pandemic. This is described in the following paragraph. Hence, the participants the trial was divided in two subsets: one subset of participants who had completed post intervention follow up assessment before the COVID 19 lockdown, on the 12^{th} of March 2020, and one subset of participants who had completed post intervention follow up assessment after the COVID 19 lockdown. Within these two subsets, differences between the intervention group and the control group were analyzed, using the t-test for independent samples.

MODIFICATIONS DUE TO THE COVID-19 PANDEMIC: As the timeline in figure 4 below indicates, the RCT was partly conducted during the COVID-19 pandemic. In Denmark, there was a lockdown, the 12^{th} of March 2020, where face to face contacts in community mental health centers and municipality mental health services were restricted. The ongoing MA&R interventions (n=2 groups) were put on hold in this period, and re-started in late May/early June 2020, where the COVID-19 lockdown was re-placed with restrictions in the community. The pandemic did not directly affect the conduction of the RCT, as the trial adhered to the recruitment, randomization and data collection procedures described in the protocol (paper 3). However, the COVID-19 lockdown and restrictions affected the interventional context, especially limiting the range and variety of opportunities for occupational engagement in the community. For instance, many structured activities, such as sports clubs and fitness centers were closed in this period. Accordingly, the participants could not always engage in the activities that they wanted to. These circumstances modifying intervention delivery were deemed important enough to undertake a subgroup analysis, examining the between group-differences among the subset of participants who had completed follow up assessments, before the COVID 19 lockdown, and the subset of participants who had completed follow up during the COVID 19 pandemic (lockdown and restrictions).

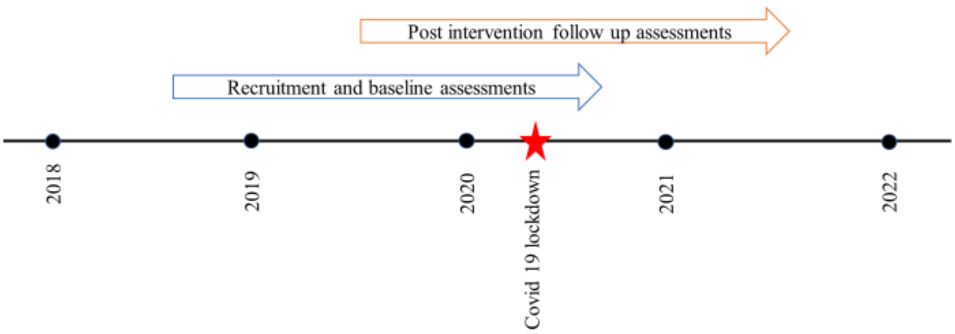


Figure 4: Timeline over data collection in study period, in relation to the COVID 19 pandemic (copied from paper 4)

ETHICS APPROVAL: The RCT was approved by the regional committee of ethics (H-1801 7307) and the Danish Data Protection Agency (VD-2018-299). The protocol was registered and uploaded at http://www.clinicaltrials.gov/ (Protocol NCT 03963245). All data were collected, stored, and processed according to GPDR. The RCT was performed according to the Helsinki Declaration. Participants` written, informed consents were obtained prior to enrollment.

3.4.2 A qualitative evaluation of MA&R

The RCT design does not provide information about the content of intervention implementation, how contextual factors impact and are impacted by the interventions, and whether there are outcomes of the intervention, other than the ones proposed in the study`s hypothesis. (110) To interpretate findings from the RCT and inform program theory development and intervention refinement, (108) participants experiences and perspectives on MA&R, and how they perceived their occupational engagement during the intervention were investigated. To explore and better understand individual-level differences, and to learn more about how the intervention worked, or perhaps not worked, we found it appropriate to conduct a qualitative study.

The aim of the qualitative study was to investigate the participants experiences of the potential impact of MA&R on occupational engagement and to explore how MA&R`s focus on activities supported the participants' recovery process.

METHODOLOGICAL CONSIDERATIONS: In qualitative research, it is acknowledged that the researcher`s background and position affect the research process, for instance the angle of investigation and judgement of which findings are relevant. Malterud states that in qualitative research, the effect cannot be avoided, but accounted for.(123) I was heavily involved in developing and partly delivering the MA&R intervention, and in designing and conducting the RCT. Hence, I considered myself being too absorbed in the field to keep an appropriate critical distance. I believe, under these conditions, it would be difficult for me to maintain reflexivity throughout the process. Hence, I deemed that if a qualitative study of MA&R was undertaken, I should not be the primary investigator. Malterud proposes that multiple researchers can, depending on positions and perspectives, access different, through equally valid interpretations of the subject being studied, thus increasing the understanding of a complex phenomenon. (123) Furthermore, Malterud also states that reflexivity involves the perception and interpretation of the same phenomena from different angles, enabling the researchers to acknowledge their role and how their research is situated. (164) During my change of research environment, I was fortunate to affiliate to University of Southern Denmark, and Dr Jeanette Reffstrup Christensen, (JCR) Associate Professor and Head of Studies for Master of Science in Occupational Therapy. Together with Dr. Christensen, I supervised Nanna Kaas Tepavicharov, (NKT) who was a student at Studies for Master of Science in Occupational Therapy, in conducting a qualitative study of MA&R. In my role as a co-supervisor, I was involved in designing the study, contributing to formulating the research question, choice of data collection and analysis strategy. For analysis strategy, Systematic Text Condensation (STC) was chosen. STC aims to identify themes across cases (interviews), and proposes a step by step strategy for analyses; overall impression, decontextualization (identifying meaning units) coding, synthesis, and recontextualization (165)

I helped NKT in recruiting, facilitating contact between NKT and participants. I was aware that I had a gate keeper role in the recruitment phase. Consciously or unconsciously, I could have given priority to participants who were positive to MA&R. I attempted to avoid this in the sampling strategy, aiming for participants who were completers and non-completers, in addition to variation in age, sex and recruitment sites. Unfortunately, among the participants who discontinued MA&R, one participant declined, and the others did not respond to my invitation. I received two or three interview transcripts from NKT and coded those independently, before meeting with NKT for discussing and comparing codes. NKT coded the rest of the interviews independently, and subsequently performed the next steps in analysis, with supervision from Dr Christensen and me.

4. Results

This chapter describes the results from the studies related to the development and evaluation MA&R. The results are presented in paper 1, 2, 4 and 5. Paper 3, the study protocol paper was presented in section 3.4.1. First section in this chapter presents the findings from the scoping review, conducted to identify, and assess studies investigating the effectiveness of occupational therapy interventions in mental health. Then follow findings from the qualitative synthesis investigating transfer from psychosocial interventions to everyday life in the community, seen from the participants` perspectives, and an outline of how the findings were applied in the development of an initial program theory, suggesting potential change mechanisms in MA&R. Next, MA&R is described, according to the TIDieR checklist. Results from the RCT are presented, before findings from the qualitative study on participants experiences with occupational engagement during MA&R.

An overview of the results presented in this section and how they related to the overall process of developing and evaluating MA&R is provided in figure 5

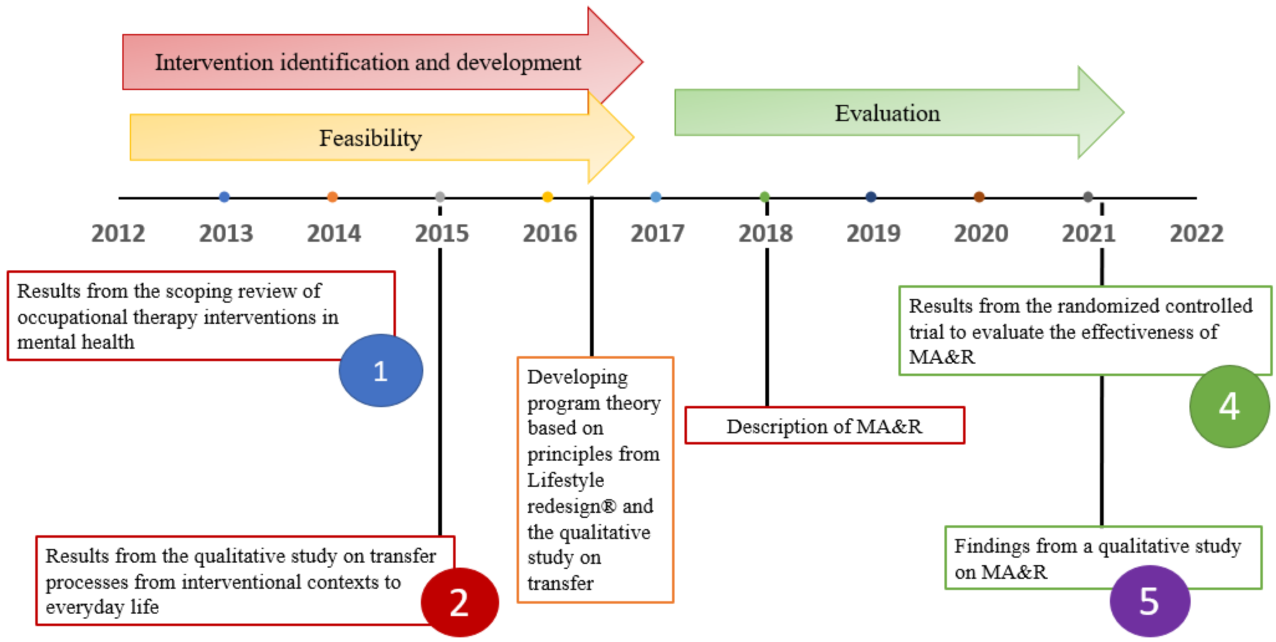


Figure 5: Results from the research activities undertaken in the development and evaluation of MA&R. Circles indicate that the results are reported in papers

4.1. Results from the scoping review and an updated literature search

Summary of results in paper 1 (Appendix I). The literature search produced 4 systematic reviews and 21 original studies meeting the eligibility criteria. Eleven of the original studies were ranked as level 2 on the OCEBM Levels of evidence ranking system, however most were pilot RCTs. 4 studies were large-scale RCTs, two investigated the effectiveness of lifestyle interventions (155,166) one was a return-to-work intervention (167) and one was an intervention to tailor activities in day centers.(168) Promising results were found for individual occupational therapy on social functioning, and the group-based lifestyle intervention showed an increase in occupational engagement. (108)

An updated search in June 9th 2022, resulted in six systematic reviews (169–173), four RCTs (174–177), a pilot RCT (178), a follow up study (179) and a study with a *"nonequivalent control group pretest-posttest design"*(180) An updated overview of the included papers, is provided in appendix IV. They are presented in tables that follow with the same headlines, as the ones in the scoping review. (108)

An overview of the original studies, after the updated literature search, revealed that people with psychosis and schizophrenia were the most frequent target groups in the studies. Fifteen studies included persons with schizophrenia spectrum disorders or psychosis, followed by studies including participants with severe mental illness, psychiatric disabilities, or psychiatric symptoms (n= 8) or with depression and/or anxiety disorders (n=6). The studies were conducted in a wide range of mental health settings, such as inpatient units, outpatient clinics, community mental health centers, day centers, general practices, occupational rehabilitation settings and/or in the community. In 7 studies, the interventions were activities (e.g., arts, crafts, music, horticulture, water exercise). In some studies, activities were parts of interventions including other elements, e.g., motivational interviewing. The interventions were either compared to usual care, or to each other, e.g., subject chosen vs. therapist chosen activities. In 5 studies, interventions consisted of programs targeting skills and strategies for engaging in everyday activities, for instance cooking, grocery shopping, money management and using a computer, and were delivered in clinics or in hospitals. Some utilized training in real world environments or added components of neurocognitive training sessions. In 3 studies, interventions (an occupational therapy consultant model, an individualized occupational therapy intervention, and work sheets designed to collaboratively develop a rehabilitation plan) were delivered in the participants homes and local communities. Five interventions encompassed work or education-related activities (return-to-work intervention, vocational rehabilitation program, cognitive work hardening program and supported education program). At least 3 interventions included elements of psychoeducation, self-management strategies etc. One intervention focused on healthy lifestyles (nutrition, exercise), others included healthy lifestyle as a part of their curriculum (e.g., BEL). 3 interventions focused on time-use, occupational balance, and occupational engagement, 2 of them were delivered as group-based interventions, and one was delivered as an individual intervention. All 3 interventions were manualized, and at least 2 of them included worksheets or a workbook. One intervention was based on life story telling and painting, and one intervention was a tool for tailoring activities in day centers. Outcomes in the studies were occupational, health related and psychological outcomes. Occupational outcomes included occupational engagement, occupational balance, occupational performance, IADL, independent living skills and satisfaction with daily occupations. Health related outcomes included global functioning, social functioning, social interaction skills, various symptoms measures, re-hospitalizations, medication adherence. Psychological measures included quality of life, cognitive functioning, executive functioning, motivation, coping, self-efficacy. Other outcome measures included work ability, proportion in productive roles (education, work, or vocational program), housing status and client satisfaction with treatment. Study designs applied to investigate the effectiveness of the intervention varied from single group design with pre-posts assessments (n=2), an economic evaluation (n=1), quasi-experimental design (n=5), follow up studies (n=4), an experimental design with repeated measures (n=1), pilot RCTs (n=4) and RCTs (n=11). The number of participants in the studies spanned from 10 to 226. Among the RCTs 3 studies had less than 100 participants (range 26 -68), while 5 RCT had between 100 and 150 participants (range 108-138) Two RCTs had 170 and 226 participants, respectively. Notably, 6 of 11 papers on RCTs were published between 2017 and 2022, indicating a steady progression of research to inform occupational therapy practice within mental health. (108,169–174,176–180)

4.2. Results from the qualitative synthesis on transfer

Summary of results in paper 2 (Appendix I)

PARTICIPANTS: A total of 39 participants were included in the synthesis. 15 participants came from the qualitative study of IMR (143), 12 participants came from the qualitative study of IPS (144) and 12 participants were recruited from LTAD and “Vendepunkter”, 19 of the participants were men and 20 were women, however the distribution varied across intervention, with most women in the IMR and peer-led groups and most men in the IPS group. Participants aged from 26 to 80 years. 8 participants, all from the IMR study lived in supported accommodations. More than half of the participants in the IPS group and peer-led program group worked, studied, or had internship. In the IMR group, one participant worked. Participants in the IMR and IPS study had severe mental illness, while the psychiatric diagnoses among participants in programs led by peer-workers encompassed both severe mental illness and common mental disorders. (142)

SUMMARY OF FINDINGS: Participants from IMR and the peer led programs, valued the interventions` group-based format, for over time, becoming a safe space for personal learning and growth: where one could reconnect to interests, values and aspirations, rediscover, practice and build on social capacities and confidence, and express and be confirmed in one`s uniqueness and worth as a person. The motivation for joining the IMR and peer-led groups varied among participants. For some, the main purpose of entering the groups, was to meet others “in the same boat” for connectedness and shared understanding of daily life challenges imposed by mental illness.

Findings indicated that peer-support was important for participants transferring what they learned during the programs, to their everyday lives in the community. Peer-support took place when engaging in conversations and dialogue with other participants during group sessions. This built greater confidence in participants, which then was transferred to daily life by making them more present and relaxed among their families and friends, and more assertive in their encounters with professionals. For participants in the peer-led program, peer-support was also perceived when the peer-worker shared personal experiences, with mental health problems and ways that they had managed those. Participants felt that they could mirror themselves in the peer-workers experiences, inspiring them to develop and try out strategies of their own. This increased self-care in daily life, e.g., to go gentler on oneself on the hard days or to say no thankyou to an invitation, without fear of hurting the inviter.

Transferring goals and plans articulated during group sessions to concrete actions and activities in daily life was not an easy task and sometimes impossible. Participants struggled with impairments imposed by the erratic and often intrusive nature of the illness, but also with lack of understanding and acceptance from the society. Symptoms such as anxiety, delusions or sleep problems interrupted daily rhythms and structure, and for some participants also interfered with intervention attendance. Real-world challenges such as dependence on social benefits and loss of social belonging, education, and work opportunities stood out as a harsh contrast to the safe atmosphere that nurtured hopes, resources, and connectedness in the group sessions. Conversely, findings also showed that engaging in real world activities, especially work and education, could be a platform for personal growth, for utilizing personal resources and for building self-belief and identity. This could "spark off" a positive spiral, e.g. as taking up a hobby or improving daily routines. Individualized support could assist participants in pursuing educational and vocational goals. The participants found it important that the support that was offered was a) timely and flexible, meaning that it could be adapted according to their plans and needs, b) that it was trusting, authentic and personal, meaning that participants first and foremost felt being met as an individual and not a client and the employment specialist was perceived first and foremost as a person and not a professional and c) that the employment specialist had competences in e.g. navigating complex welfare systems and d) that the employment specialists could balance when to "step back", letting the participant taking the lead in the job search process, but also be there for support and encouragement.

4.3. Developing program theory

As previously described, the qualitative synthesis was performed to inform further development of MA&R by seeking to identify core components that could impact occupational engagement. Blasé and Fixen defines core components as *"essential functions or principles, and associated elements and intervention activities, that are judged necessary to produce desired outcomes."*(181) Core components can either be theoretically or empirically driven. The core components that informed the development of MA&R were both, as they were based on dynamic system theory (Lifestyle redesign®) (136), transfer theories (137,138), and the findings from qualitative synthesis. (142) Core components consist of *core functions*, which are the basic purposes or the effects, that the intervention seek to facilitate, and *forms*, that are the specific activities or strategies necessary to carry out the achieve this effect. (182) According to the founders of Lifestyle Redesign ®, a central principle was that gaining greater knowledge about the occupation-health/wellbeing relationship, would enable the participants to re-order their occupations into healthy, stable patterns, despite age-related decline. Hence, 1) providing information about and 2) direct experiences with activities were two core components of Lifestyle Redesign ®, facilitated by didactic presentations, peer-exchange, direct experiences with activities and personal exploration. (136) Core components, developed based on findings from the qualitative synthesis and incorporated into the MA&R intervention were:

3) Group sessions are delivered in a safe atmosphere, to inspire participants to reflect upon occupations, practice social interactions and build confidence.

4) Sessions are facilitated by a peer-worker and an occupational therapist. Experiential knowledge is utilized, in addition to an occupational perspective on health, to enhance transfer from interventional context (group sessions) to daily life in the community.

5) The intervention is delivered in an authentic and respectful mode, to build trusting relationships. The occupational therapist and the peer-worker are equal contributors at the group sessions, both drawing on personal experiences when presenting the topics.

6) Group sessions are combined with individual sessions, where the participant meets with either the peer-worker or the occupational therapist, for a more personal orientation and for enhancing flexibility and continuity for participants who due to unstable illness periods or other reasons, cannot attend group meetings regularly.

7) Engaging in activities that are perceived as meaningful, in one`s home or community has a positive “spillover effect”, enhancing initiatives, routines and variation in everyday life.

8) Individualized support is offered in the home, community, or any place the participants prefer, if the participants wish so, to explore, initiate, practice, and sustain activity engagement, during MA&R.

These eight core components suggested potential change mechanisms in the MA&R, and proposed intervention delivery forms that would lead to increased occupational engagement. In this context, they served as the building blocks for developing a preliminary program theory of MA&R. As figure 6 depicts, the core components encompassed core functions, that were facilitated by one or more forms (intervention activities). In this initial program theory, it was expected that if MA&R increased occupational engagement, it would also lead to improvements in areas associated to occupational engagement: quality of life (24,73), personal recovery (76) and functioning.

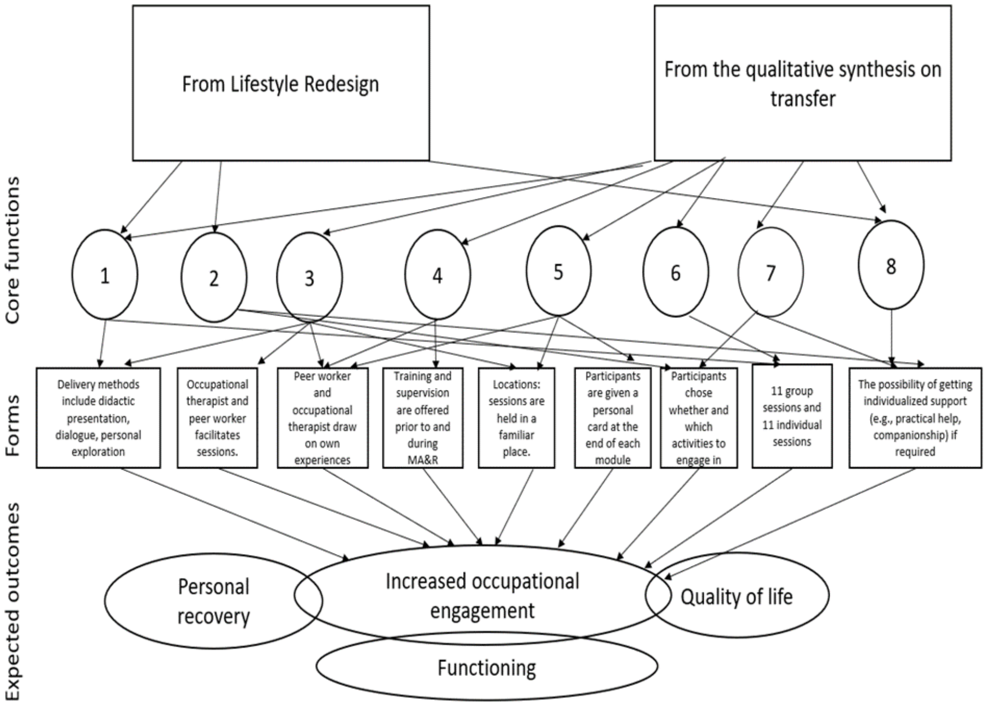


Figure 6: Developing an initial program theory: Core functions, forms and expected outcomes.

4.4. Description of MA&R

Meaningful Activities and Recovery is described according to the TIDieR checklist, covering the intervention´s name, rationale and theory, materials, procedures, provision, tailoring, modification and fidelity.(161)

1. <u>Name:</u> Meaningful Activities and Recovery (MA&R)

<u>2.Rationale and theory:</u> Activity and participation are human needs, and crucial aspects of health and wellbeing. Psychiatric disabilities occur, when people due to their mental health conditions (e.g., intrusive symptoms), social consequences of mental illness (stigma, marginalization), and lack of accommodation in society (limited access for social support) are inhibited in participating in the daily activities that they need or want to. Re-engaging in activities that the individual finds meaningful, can be important for recovery, personal growth and for breaking out of a downward, disabling spiral of inertia and isolation. An activity oriented, group-based intervention, that incorporates formal and informal peer-support and individualized support may assist people with psychiatric disabilities in occupational engagement, in everyday life.

<u>3.Materials:</u> MA&R is a manualized intervention. The material consists of a) The MA&R guide, describing the MA&R program rationale, underpinning core components, values (occupation, wellbeing, self-determination), the roles of the occupational therapist and the peer-worker and their unique positions in the program, preparing for the MA&R sessions, and examples of individualized support, b) The MA&R manual with guidelines and descriptions of the sessions aims, format and content, c) Power point presentations to

support didactic presentations in group sessions, d) workbooks with printed versions of the slides presented at group sessions, questions to inspire personal reflections and explorations, and sheets for making notes, e) Dialoogle cards (cards with pictures to inspire to reflection and dialogue at group sessions), f) cartoon papers to make cards with personal greetings from the occupational therapist and the peer-worker to participants. The MA&R guide, manual, workbooks, and PowerPoint presentations can be accessed by contacting first author, Dialoogle card can be purchased online at https://dialoogle.com/da/.

4. Procedures: MA&R is delivered as 11 group sessions and 11 one on one sessions, that takes place interchangeably. The program comprises two modules (MA&R I and MA&R II), the first module with two weekly sessions, and the second module with two monthly sessions and opportunities for individual support. The peer-worker and the occupational therapist prepare themselves before group sessions, individually and/or together. Preparation includes planning the sessions and discussing lived experiences that could serve as examples in didactic presentations. On site preparations involve sending a text message to the participants with a reminder (only for group sessions), making coffee and tea, arranging tables, chairs, flip overs and PowerPoint presentations. During COVID 19, preparation also involved cleaning the equipment used before and after each group session. Overall, each group session follows the same steps: 1. Welcome and introduction to the topic of the day, 2. Check-in round, 3. Didactic presentations, 4. Individual work in the workbook, 5. Dialogue and peer-exchange 6. Round-up and goodbye. Each individual session follows the steps: 1. Catching up since the last group sessions, 2. Reflections on the topic, 3. Other issues important to the participant, 4. Preparation for the upcoming group session. No guidelines are described for individual support, as this is defined by the needs and preferences of the participants. Examples of support are conversations/relational support, companionship, practical help or finding opportunities for activities in the community.

5. Who provided: The providers of MA&R are an occupational therapist, employed in mental health, or with a work experience from mental health, and a peer-worker with lived experiences of mental health problems, recovery, and occupations. Training of providers involves a 3-hour introduction to MA&R, in addition to both providers reading the MA&R guide and screening the manual. Moreover, the providers received 6 x supervision during MA&R, in the MA&R method, each supervision session lasted between 90 and 120 minutes.

6. Mode of delivery: MA&R is delivered in a group-based and individual format. Group size varies between 4 (minimum) and 10 (maximum) participants. Participants can communicate with the occupational therapist and the peer-worker between sessions (phone number is provided) and they also received a text message on the day for group sessions with a reminder.

7. Where: MA&R is delivered in the same community mental health center or in the municipal mental health service center. Group sessions is delivered in an eligible room, with space enough for at least 12 persons (or

less if fewer than 10 participants in a group) and with the appropriate requitement to deliver didactic presentations (e.g., PC, overhead, whiteboard etc.). The individual sessions are either held in an office at the community mental health center, or in the municipal mental health service center, or in the participants homes or near surroundings, depending on the participants preferences. Individual support can be provided in the participants` homes, sports clubs, parks, cafes or the job center, or other places depending on the purpose and nature of support.

8. When and how much: Sessions are delivered about twice weekly in the first module, MA&R I (about two months) and about twice monthly in the second module, MA&R II (between five and six months). Group sessions last 90 or 120 minutes and individual sessions between 30 and 60 minutes. No upper limit is set for individual support, but a rough estimate of hours spent on induvial support, made by the researchers, is an average of 2 hours pr. participants pr. month in MA&R II.

9. Tailoring: The MA&R intervention is tailored to each of the participants in a close dialogue between the participant and the occupational therapist/peer-worker. There is no lower threshold for how few group sessions or individual sessions the participant can attend. For instance, some participants only participate in individual sessions, with the occupational therapist or the peer-worker. The individual sessions enhance the delivery of a personal approach and the adaption of MA&R according to participant`s needs and current situation, e.g., one can derive from the curriculum, if there are more urgent matters for the participant to address, and individual needs can be taken care of (e.g., difficulties in interactions with other participants in the group) Furthermore, individual support is optional and tailored to the participants preferences and needs.

10. Modifications: No modifications of MA&R were done, during the study.

11. Assessing fidelity: A MA&R fidelity scale is developed, by the occupational therapist/developer of MA&R and a member of the research team, Bea Kolbe Ebersbach who has experience with fidelity scales and assessing fidelity. The purpose of the fidelity scale is to assess how well the MA&R is delivered according to the intervention’s values (occupations, wellbeing, and self-determination) and principles (equality, learning, collaboration, and support). The MA&R fidelity scale consists of six items, each item was rated and given points according to pre-specified criteria.

The items are

- Providers (expertise, training, and supervision)
- Organization (number of participants, location, individual tailored learning, modes of delivery)
- Group-sessions (material, content, methods of delivery)
- One-on one sessions (content, involvement of significant others, personal greeting)
- One -on one support (individualized)

- Outreach (when absence without notice)

Fidelity assessment are conducted once, pr. MA&R group, at the end of the intervention (often in conjunction with last group session). All participants are invited to participate in a focus-group interview, and the MA&R providers are interviewed individually. All fidelity assessments are conducted by external assessors, who are trained in conducting fidelity assessments and are not members of the research team. The points from each item are added to a total score, reflecting how well the MA&R intervention was implemented. The range and cut offs in the MA&R fidelity scale is depicted below.

<25	Not MA&R
26 – 32 point	OK MA&R
33 – 38 point	Good MA&R
39 – 41 point	Optimal MA&R

12. Actual Fidelity: Adherence and fidelity scores for each site and MA&R group, will be presented in the next chapter, covering the results from the MA&R trial.

4.5. Results from the RCT

Summary of results in paper 4 (Appendix I)

PARTICIPANT FLOW: Between 2018 and 2020, 180 persons were assessed for eligibility. Among those were 41 excluded, mainly because they declined to participate in the study. 139 participants were enrolled and randomly assigned to either MA&R + standard mental health care (n=70) or standard mental health care (n= 69). Three participants declined to participate in MA&R after randomization, and 9 discontinued the intervention. At post intervention assessment, 12 participants in the intervention group and 14 participants in the control group were lost at follow up. This corresponded to a follow up rate of 82 % and 79 % respectively. There were no significant differences between responders and non-responders in demographic characteristics, disability levels, or baseline measures. All participants were included in the intention to treat analysis. (Figure 7, CONSORT flow diagram)

BASELINE: About 50 % of the 139 participants were men (n=68). The mean age was around 43. Most were single, did not have children, lived alone, and were not affiliated with the labor market. Schizophrenia spectrum disorders were the most frequent reported diagnosis, among participants, followed by depressive disorders and anxiety disorders. The mean MINI-ICF-APP Score corresponded to a moderate grade of disability. No statistical differences were found between groups, in demographic characteristics, levels of disability or baseline measures. We deemed that the random allocation was equally balanced with no significant differences between groups. A detailed description of characteristics of the study sample, can be found in table 2 in paper 4

ATTENDANCE: 58 participants (82,8 %) completed MA&R. Mean attendance among participants was about 15 sessions (SD: 5,7), distributed on 7 group sessions and 8 one-on one sessions. 40 participants received individual support. They had in average 2,8 encounters (SD 2) with either the occupational therapist or the peer-worker.

FIDELITY: A total of 10 MA&R groups were conducted between September 2018 and May 2021. Three sites conducted two MA&R groups, and four sites conducted one MA&R group. All groups were completed. More participants (about 60 %) were recruited from the community mental health centers than from the municipal mental health service centers. 5 of the MA&R groups were conducted between March 2020 and May 2021, during the COVID 19 pandemic. Fidelity assessments showed that three MA&R groups were delivered with good fidelity, and seven was delivered with optimal fidelity, according to the MA&R fidelity scale. A detailed overview of the fidelity scores for each MA&R group at the sites is presented in supplementary material, in paper 4

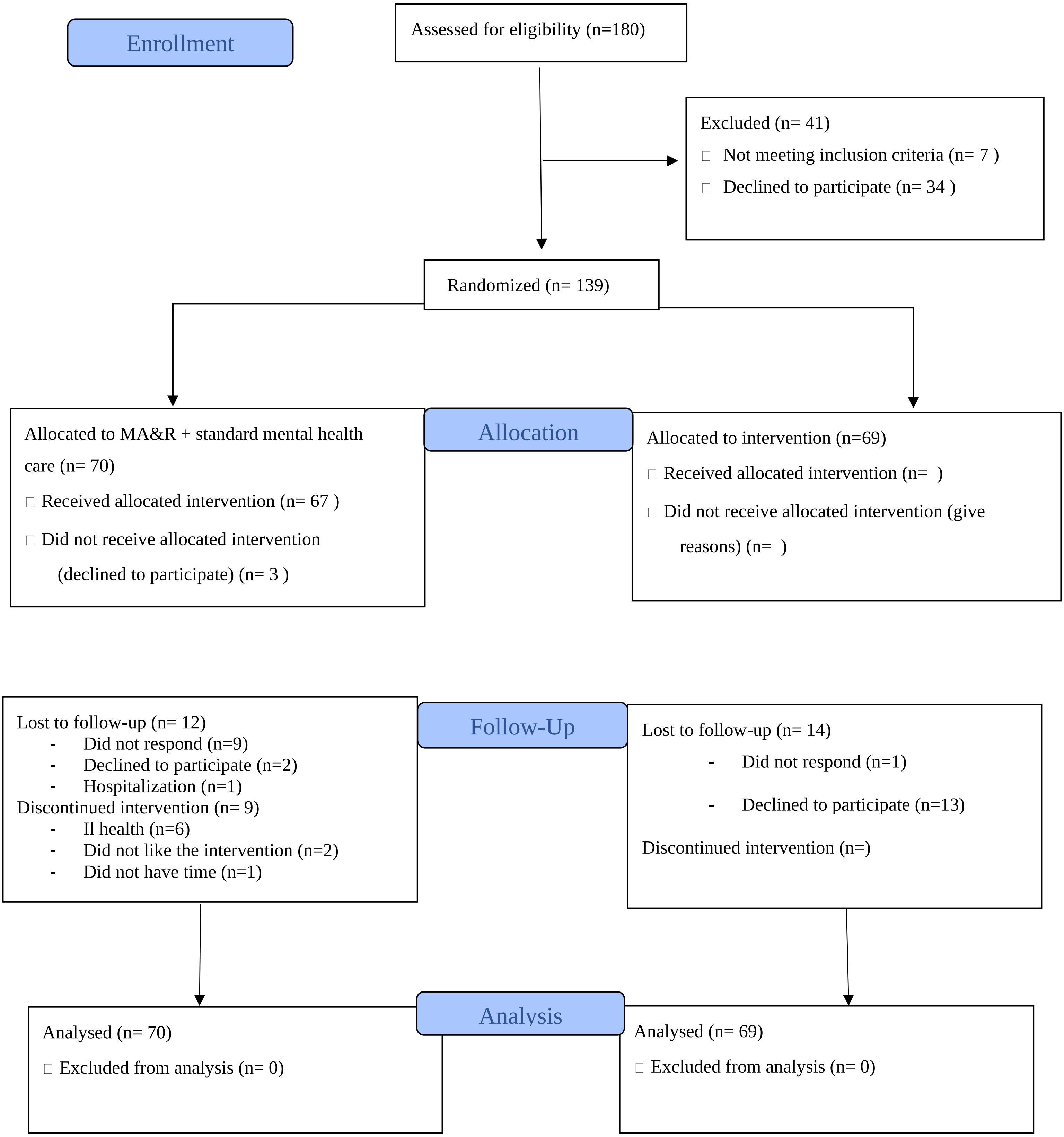


Figure 8: CONOSRT Flow diagram

OUTCOMES: At post-intervention follow up, the statistical analysis showed that there was no significant difference between the intervention group and the control group, on the primary outcome, activity engagement. Moreover, no significant differences between groups were found in functioning, personal recovery, or quality of life. These results can be found in the two columns at the right in table 4, below.

	MA&R + standard mental healthcare				Standard mental health care					
Outcome measures ↓/↑ indicates preferable outcome↑	**T0**	**T1**	**T0-T1 Within group**	**p-value**	**T0**	**T1**	**T0-T1 Within group**	**p-value**	**T1-T1 Between groups**	**p-value**
	Mean (SE)	**Mean (SE)**	**Est. (95% CI)**		**Mean (SE)**	**Mean (SE)**	**Est (95% CI)**		**Est (95%CI)**	
Occupational engagement										
Profiles of Occupational Engagement in People with Severe Mental Illness – Self report	21,17 (5,26)	23,73 (0,72)	2,55 (1,4, 3,7)	0,000	21,13 (5,57)	22,58 (0,88)	1,45 (0,05, 2,85)	0,04	1,14 (-1,09, 3,337)	0,315
Functioning										
WHODAS 2.0 12 item ↓	31,25 (7,59)	29,45 (1,26)	-1,79 (0,58, -4,16)	0,138	29,59 (7,45)	27,53 (0,93)	-2,06 (-0,34, -3,77)	0,019	1,92 (-1,1, 5,03)	0,23
WHODAS 2.0 11 item (without work item)	28,46 (6,97)	26,92 (1,13)	-1,5 (0,57, -3,65)	0,153	27,13 (6,87)	25,07 (0,88)	-2,05 (-0,42, -3,68)	0,013	1,84 (-0,98, 4,67)	0,20
WHODAS 2.0 36 item ↓	56,29 (17,84)	50,28 (3,1)	-6 (-0,35, -11,66)	0,037	53,75 (19,44)	46,9 (2,8)	-7,3 (-2, -12,6)	0,007	3,38 (-4,83, 11,59)	0,42
WHODAS 2.0 domain score *Cognition* ↓	14,81 (3,88)	13,82 (0,65)	-0,9 (0,27, -2,27)	0,123	14,39 (4,6)	13,25 (0,55)	-1,14 (0,11, -2,36)	0,075	0,66 (-1,02, 2,35)	0,44
WHODAS 2.0 domain score Mobility ↓	10,44 (4,1)	9,92 (0,59)	-0,52 (0,66, -1,7)	0,38	9,22 (3,9)	8,98 (0,46)	-0,24 (0,52, -0,99)	0.544	1,04 (-0,46, 2,54)	0,173
WHOADS 2.0 domain score Self-care ↓	7,8 (3,1)	7,56 (0,42)	-0,24 (0,58, -1,05)	0,56	7,46 (3)	7,21 (0,37)	-0,25 (0,51, -1,01)	0,517	0,35 (-0,75, 1,45)	0,53
WHODAS 2.0 domain score G*etting along* ↓	14,47 (4,46)	14,14 (0,6)	-0,33 (0,69, -1,35)	0,53	14,08 (3,9)	12,59 (0,6)	-1,53 (-0,32, -2,74)	0,013	1,55 (-0,095, 3,2)	0,065
WHODAS 2.0 domain score Life activities (Household)↓	12,26 (4,15)	11,16 (0,6)	-1,07 (0,11, -2,26)	0,07	12,14 (4,32)	10,83 (0,58)	-1,4 (-0,34, -2,47)	0,009	0,28 (-1,41, 1,97)	0,742
WHODAS 2.0 domain score Participation↓	24 (5,16)	22,08 (0,8)	-1,9 (-0,45, -3,38)	0,01	23,67 (5,12)	21,1 (0,83)	-2,59 (-1,04, -4,12)	0,001	0,99 (-1,29, 3,26)	0,4
Personal recovery										
Questionnaire about Recovery Processes 15 ↑	32,24 (11,53)	36,61 (1,3)	4,37 (1,99, 6,77)	0,000	32,33 (10,46)	35,05	2,71 (-0,4, 5,84)	0,08	1,56 (-2,59, 5,71)	0,46
Quality of life										

Manchester Short Assessment of Quality of Life ↑	47,76 (9,62)	51,24 (1,54)	3,2 (0,62, 5,8)	0,014	46, 32 (10,33)	50,8 (1,54)	4,3 (1,36, 7,25)	0,004	0,44 (-3,86, 4,73)	0,84
EQ-5D-5L: EuroQol Five Dimensions Questionnaire with Five Levels ↑	0,61 (0,22)	0,62 (0,03)	0,007 (-0,04, 0,06)	0,765	0,63 (0,17)	0,64 (0,02)	0,01 (-0,03, 0,06)	0,425	0,02 (-0,10, 0,49)	0,49
EQ-5D-5L Health index	53,61 (20,9)	58,08 (3,06)	4,48 (-1,4, 10,35)	0,136	55,51 (23,71)	58,32 (2,89)	2,7 (-3,66, 9,17)	0,4	0,24 (-8,4, 7,92)	0,95

Table 4: descriptive and inferential analysis of MA&R + standard mental healthcare and standard mental health care at baseline (T0) and at post intervention follow up (T1).

Post hoc analysis of within group changes, showed that both intervention group and control group improved over time in occupational engagement and in quality of life, measured by MANSA. Both groups also improved in functioning, measured by WHODAS 2.0 36, but only improvements in the control group were significant, in WHODAS 2.0 12. The control group had significant improvements in the *getting along* domain, and the *household* domain. Both intervention group and control group, improved in the *participation* domain. Only intervention group improved in personal recovery. No significant improvements were found in health-related quality of life, in any of the groups. (Table 4)

In comparison of the subsets of participants completing post intervention follow ups, before and after the COVID 19 lock down, we found a between group difference of 2,8-point (p=0,064) on POES-S favoring the intervention group, before the COVID lock down, and almost no difference between the intervention group and the control group, after the COVID 19, lock down. Notably, the mean POES-S score did not differ among the two subsets of participants in that participants in the intervention group before or after COVID 19 lockdown, both scores being around 23, whereas in the control group, higher mean score on POES-S was found in participants, after the COVID 19 lockdown than before the lockdown. (20,81 vs 23,68) (Table 5)

	MA&R + standard mental health care	Standard mental health care	Est (95% CI)	p-value
Before COVID 19 lockdown	23,77	20,81	2,85 (-0,16, 5,88)	0,064
After COVID 19 lockdown	23,94	23,68	0,1 (-2,98, 3,19)	0,94

Table 5 displays mean POES-S scores at post intervention follow up, before and after the COVID 19 lock down.

4.6 Results from the qualitative study

Summary of results from paper 5 (Appendix I)

PARTICIPANTS: 10 men and 3 women participated in the study. They had completed MA&R, between 0 to 12 months prior to the interview. Participants varied in age, the youngest being in his early twenties, and the oldest in their early fifties. Most had psychosis or schizophrenia spectrum disorders, others reported to have depression, anxiety disorders, stress, ADHD, personality disorders or did not know their psychiatric diagnosis. Four participants were students, one was in job training and seven participants were either unemployed, job searching or received early retirement pension at the time when the interview took place.

SUMMARY OF FINDINGS: Change in occupational engagement during MA&R was perceived as a process of finding meaning and value in the "ordinariness" of everyday life. First and foremost, it entailed participants developing a new "lens" on meaningful activities. Learning about occupations, recognizing that activities could have several forms and purposes and could encompass different meanings to different people, was highly valued. Occupational engagement was facilitated by participants identifying activities "*right at their grasp*", activities that were already within their reach, so to say. The activities were generally close to home and mundane, often overlooked or taken for granted, e.g., make the bed, air out the bedroom, water the plants or do the laundry. Changes occurred in the meaning and value ascribed to these activities, as they provided experiences of recovery and became building blocks to better daily life. Participants learned during MA&R that smaller and familiar things could have catalyzing effects, e.g., enhancing presence, curiosity, immersion, and joy. Reflection and exploration of activities, e.g., noticing when an activity felt good or draining and engaging in activities in a trial-and-error mode, was motivating and encouraged participants to try out new things, to initiate doing, without worrying about the "output" being successful.

Contrary to the anticipations about change mechanisms in MA&R, peer-support in terms of group interactions and individualized support in terms of companionship and practical help was not highlighted by the participants as crucial for change in occupational engagement. As far as informal peer-support is mentioned in the findings, perceived differences between informant and the other participants in the group was identified a barrier for engagement in MA&R. In respect to individualized support, some participants expressed disappointment for not receiving the practical help that they urged for (e.g., assistance with searching for a new place to live), or that practical support was restricted by the COVID-19 lockdown (e.g., go swimming, find a tutor for writing a book). Formal peer-support (the role of the peer-worker) and the individualized approach (receiving a personal postcard, one-on one sessions) were highlighted by the participants as fundamental for their engagement in MA&R. Many participants stated that the lived experiences of the peer-worker, helped them draw parallels between the content in MA&R to their own lives, giving them new perspectives on what was possible for them (e.g., opportunities for becoming a peer-worker themselves). The participants also highlighted the personal approach in MA&R, and the tone of the peer-worker and occupational therapists, which they perceived as collaborative, respectful, and authentic, for essential for their engagement in the intervention

Findings also suggest that occupational engagement involved a change in the way that the participants saw themselves in relation to their doings. They softened up a black or white self-image, not being ashamed of one`s disabilities. Becoming more aware of initiating activities that was perceived as meaningful and did not exceeded one`s capabilities, strengthened the participants self-determination and reduced comparison with others. Participants described an increased awareness of activities becoming a part of their personal toolbox of resources, a relief from symptoms or distress and a confirmation of that they were able to enjoy their doings and reach a state of flow, where they became immersed in their occupations, just like anybody else.

Findings indicate that change in occupational engagement, was mostly experienced as an individual journey. As far as environments were mentioned, it often referred to participants` homes and near surroundings, such as the park, the laundromat, or the grocery shop. Social milieus were rarely mentioned, occasionally occupational engagement involved doing things with a friend or saying hello to a stranger, on the way to the shop. This might be a direct consequence of circumstances during the qualitative study, with social distancing and many opportunities for activities in the community being restricted due to COVID 19. However, the findings may also identify missing core components in MA&R. Hence, the findings raise questions about whether the intervention in its current format was insufficient to produce the intended outcomes, in terms of enabling occupational engagement in social contexts (theory failure). These aspects, among others, will be discussed in the following chapter.

5.Discussion

This chapter starts with a summary of key findings. The interpretation of the results will be addressed in two sections. Firstly, a revisitation of the development of MA&R, to discuss blind angles and suggest altered approaches to address these. Secondly, moving on to the evaluation of MA&R, the null results from the RCT are discussed, and together with the findings from the qualitative study, reviewed to propose a refinement of MA&R`s program theory. Then, methodological limitations are discussed.

5.1. Main findings

In the scoping review, conducted prior to the development of MA&R, the available evidence covered multiple types of occupational therapy interventions, delivered in a variety of settings in mental health, investigated in relation to a broad spectrum of outcomes, ranging from symptoms and cognitive impairment, to functioning and quality of life. There were only few studies investigating the effectiveness of occupational therapy interventions in relation to occupational engagement and there was especially a need for rigorous, powered studies. In the process of developing MA&R, a qualitative synthesis was performed, which provided insights into how illness management skills and recovery strategies are transferred beyond the interventional context to the wider everyday life. The results put emphasis of peer-support, both formal and informal as important ingredients for transfer to occur. Accordingly, findings suggested that the skills and strategies, and perhaps most importantly confidence acquired during the interventions could be transferred to interpersonal relationships, communication, and self-care, or in areas in daily life where participants found similarities between their own and experiences of the peer-worker. The interventions had their shortcomings, as illness fluctuations and environmental barriers could limit the opportunities of pursuing recovery goals, or strategies learned during group sessions, in daily life in the community. Individual support could partly address these shortcomings, for instance by offering flexible and timely help, and relational support. The development of MA&R built on these findings, so it became a mixed intervention, combining "the best of two worlds" – with formal and informal peer-support during group session, for inspiration, motivation, confidence and skills, and individual, timely and flexible support in the community to engage in real life activities, and explore new arenas for occupational engagement. Hence, it was hypothesized that MA&R, when combining these components, would be better than the usual mental health services, when it came to enabling occupational engagement, supporting personal recovery, or increasing functioning or quality of life. The results from the RCT did not support the hypothesis. Contrary to the anticipations, they showed that MA&R was not superior to usual mental health services, in respect to occupational engagement, nor any of the other outcomes. To better understand these findings, a post hoc analysis was conducted, showing that both intervention and control group improved significantly over time, in several of the outcomes. The analysis suggested a tendency that MA&R might have been better than standard mental health services before COVID-19, in enabling occupational engagement, but not during COVID-19. The qualitative study, investigating the participants experiences of occupational engagement during MA&R found that changes first and foremost meant an altered perspective on everyday activities, but not a change in actual doing.

5.2. Revisiting the development of MA&R

The development of MA&R had two underpinning frameworks: 1) key principles from Lifestyle Redesign ® (136) and 2) transfer theories.(137,138) Both frameworks highlight the process of <u>learning</u>, that acquiring knowledge and skills is essential for change. In Lifestyle Redesign®, learning enables a change in occupational patterns, in re-ordering those into stable, healthy ones, despite age related decline.(136) In transfer theories, learning is a pre-requisite for taking on professional roles, carrying out work related functions. Learning is a hallmark in many psychosocial interventions, offered to people with psychiatric disabilities, (43,88,183,184), including IMR (185) and the peer-led programs from the qualitative synthesis.(142) The purposes of these programs are to enable a learning process, where participants develop skills and strategies that can be transferred and utilized in the context of illness management and recovery. Consequently, the programs draw on educational methods. (183,185) The choice of transfer theory (137,138) and the qualitative synthesis, informing the development of MA&R, may have led to a predominant focus on learning and consequently changes in the *individual*. For instance, half of MA&R consisted of group sessions with pre-defined topics and presentations by the occupational therapist or peer-worker. The focus in MA&R on learning and individual "solutions" holds parallels to the understanding of personal recovery as, to paraphrase Prof. Anthony as "*an individual journey of changing one's attitudes, values, feelings, goals, skills, and/or roles.*"(29) As described in the introduction section, this definition of recovery has been expanded to encompass recovery as a personal process in the <u>interpersonal, material and social world</u>. In MA&R, social aspects were addressed by introducing the possibility for participants to invite family, friends or professionals to collaborate around meaningful activities during MA&R, and to support participants in engaging in activities in the community. Nevertheless, taking a critical stance, one can argue that the attempts of collaborating with significant members of the participants` network were halfhearted, as few picked up on the offer. Placing the main weight on the individual`s personal learning process, may have led to a risk of overlooking environmental approaches to enable occupational engagement. Individualized approaches are common in mental health rehabilitation services, but they have also been disputed, for instance, by Professor Larry Davidson and Professor James Mandiberg, (186–189), who argue that finding ways to help people to live successfully in their communities, demands a shift of focus from mental illness and disability to a focus on the community. (186) More empirical studies are necessary to understand features of communities in which people with psychiatric disabilities participate and thrive. In comparison, much research has been conducted in relation to dementia friendly communities. Two scoping reviews (190,191) have identified environmental designs, education and awareness about dementia, development of dementia friendly communities with access to for instance social and cultural activities and a health sector with a person-centered care and strong interdisciplinary collaboration, as important factors. (190,191) In 2021, the Danish Government allocated more than 40 million DKK, (about 5,4 million €) for finding new ways to make Denmark a more dementia friendly society. In this context I argue that initiatives and research addressing "recovery -friendly" communities, seen from the perspectives of people with psychiatric disabilities, their friends, and relatives and from professionals, seems equally warranted, in addition to interventional studies, like MA&R.

Looking back at the development of MA&R, most components (group sessions, individual sessions, photo voice activity) focused on participants acquiring knowledge about activities in relation to health, wellbeing, and recovery, identifying own meaningful activities, and learning new strategies for enabling occupational engagement. Hence, one can say that MA&R probably was designed to mainly target the person, (values and interests), in the PEO model. (55) In this context, MA&R may be different from BEL (155) and from the Lifestyle Redesign ® program, (136) that focus on mapping occupational patterns, and creating change towards more stable, balanced patterns. BEL utilized home practice between sessions, which might have addressed the Occupations in the PEO model, to a greater extent than MA&R. Furthermore, the follow along support in MA&R had a less individualized delivery format than IPS (192), as it was combined with group-and individual sessions. Although individual support was a part of MA&R to enhance transfer between group-sessions and individual sessions, to enable occupational engagement, the findings from the qualitative study indicate that most profound mechanism of change in MA&R was to narrow the focus of recovery down to meaningful activities and help the participants explore this. Accordingly, if the delivery format of individual support were less rigid, and more individualized, (for instance, without a time limit as in IPS) the support offered to the participants, could perhaps have had a stronger impact on occupational engagement.

As pointed out in the introduction section, occupational engagement does not only depend on the person, but also relies on the type of activity as well as resources and barriers in the material, and social world. As beforementioned, the environmental aspect of occupational engagement was mainly addressed by the individual support in MA&R, offering companionship, practical help, or relational support to access activities in the community. However, a scoping review conducted by Doroud and colleagues, found that places, for instance housing, material and financial resources, neighborhoods, natural environments, services, and social resources, all can contribute to or hinder recovery. The authors concluded that places offer opportunities for experiences shared values, mutual supports, interactions, and meanings, all important for the synthesis of doing, being, becoming and belonging. However, the studies did not explain how places facilitate and offer opportunities for occupational engagement. (61) Although more research is needed in the area, an enhanced focus on the environmental opportunities for occupational engagement, e.g., by joint outings, or collaboration with for instance, local sports clubs could potentially have added essential core components to MA&R

Collaborating with families, friends or other professionals depending on the participants wishes and preferences was an option, but not a part of the curriculum in MA&R. Fidelity reports showed that this seldom occurred during the intervention. Studies, for instance on Open Dialogue (193–196) have demonstrated that mental health interventions can enhance collaborations and improve conditions, related to the interpersonal and social environment. An example of network-oriented interventions is Resource Groups (RG), a model where people with mental illness chose significant others who were members from their informal and formal social network to discuss self-chosen recovery goals and together work out plans to achieve those goals. The RG model was investigated in a RCT as an adjunct to treatment delivered in F-ACT teams. Compared to F-ACT alone, the RG was superior on a broad range of outcomes, with small to moderate effect sizes: empowerment (d= 0.54; 95% CI, 0.21-0.86), quality of life (d= 0.25; 95% CI, −0.07 to 0.56), personal recovery (d= 0.38; 95% CI, 0.06-0.69), quality of social contact t (d= 0.24; 95% CI, −0.07 to 0.56) and functioning (d = 0.28; 95% CI, −0.04 to 0.59). Implementing the RG method was reported as challenging, and only 44 of the 80 participants in the intervention group had two or more RG meetings.(197) However, the findings support the importance of family and social network in recovery processes, and a lack of focus on involvement of the social network, in the development of MA&R, may have left out an important core component for enabling occupational engagement.

During MA&R, participants identified several activities that were meaningful to them and were part of their recovery goals (go hiking, travel, have heart-to-heart talks, visit cafes and museums, or enjoy cultural events, for instance movies or concerts). Not surprisingly, the participants found these activities more accessible, enjoyable, or less daunting, having someone to share them with. This critical feature of occupational engagement should perhaps have been more profoundly addressed in the development of MA&R, incorporating closer attention to the participants` interpersonal relationships or lack of same.

Improving participants social circumstances, in the context of enabling occupational engagement could have been addressed in multiple ways. For instance, by volunteer befriending, which encompass one-on one support offered through un-paid non-professional voluntaries and involves cultivating relationships, fostering companionships, e.g., by just *being together*, or *doing things together* (198). Volunteer befriending has been investigated in multiple RCTs, yielding mixed results. A systematic review and meta-analysis from 2017, found that befriending interventions did not lead to significant improvements in depression symptoms, quality of life or perceived social support, but when added all patient reported outcomes together, the author found a small, but significant effect (199) An alternative to befriending, could be to support the participants in making connections during MA&R, e.g., by adding outings or encouraging joint occupational engagement during group sessions, or organizing social media groups.

Prognostic research, for instance studies that describes the course of occupational engagement and factors associated to occupational engagement as an outcome, might also have informed the development of MA&R. (200) According to Morris and Cox, (62) occupational engagement can be viewed as a cyclical process, where positive experiences of occupations, feedback from the environment and well-being serves as a positive feedback system of ongoing occupational engagement. However, there might be other predictors, related to the person, the occupation, and the environment that facilitate occupational engagement. Also, knowledge is needed about strategies developed by the person with lived experiences or offered by supportive individuals in the persons immediate surroundings that help individual with mental illness in moving between different modes of occupational engagement. Identifying these factors, may inform the understanding of change mechanisms, and potential identifying other core components than the ones derived from the qualitative synthesis.

Although an occupational perspective on health puts emphasis on wellbeing and positive aspects of occupations, it has been stated that occupations are multi-faceted and do not solely have health promoting effects. The “dark side” of occupations, is an emerging concept within occupational therapy literature, meaning that not all occupations lead to health and wellbeing. (201) For instance, there are occupations, things people do, that are destructive and self-damaging. Also, occupations that do not enhance health, can still provide a sense of wellbeing. These aspects of occupations are less investigated and understood. Insights into occupations that are viewed to be unhealthy, undesired, unacceptable, or inappropriate may be an important advancement in relation to the simplistic approach in the occupational perspective on health and bring on more nuanced understandings of what humans do in everyday life. Research on this matter has been conducted in respect to occupations such as fighting, smoking, alcohol drinking or sex work. (202) In MA&R, participants noticed mundane occupations that were “two-sided” in a way that they were both adaptive but also problematic. An example was lying in bed, watching TV. This could be a meaningful activity with opportunities for self-care, rest, and enjoyment. However, it could also be a way of avoidance, a safe space that served well in the moment, but in the bigger picture impeded occupational engagement. In the development of MA&R, the failure to address the "dark side" of occupations, may have unintentionally shaped some social ideals around occupations that participants agreed with, but found it difficult to identify with or relate to, and thereby enhancing the experience of marginalization instead of reducing it.

5.3. Evaluation of MA&R – making sense of the null findings.

Standing on the shoulders of Karl Popper (128), we developed an a priori hypothesis about the anticipated change mechanisms in MA&R and subjected it to empirical testing in the RCT. As described in the result chapter, the null hypothesis was not rejected, meaning that an association between the tested variables (the experimental intervention and the outcomes) could not be established. MA&R was, contrary to the expectations, not superior to usual mental health services, when it came to strengthening occupational engagement, personal recovery, functioning, or quality of life.

The overall goal with the research, presented here, was to produce knowledge of "what works" when it comes to enable occupational engagement, in mental health services. The short and concise interpretation of the results was that "MA&R did not work". Nonetheless, it has been pointed out that further interpretations of null findings can yield important knowledge to inform future research.(203–205) A null finding can be defined in multiple ways, for instance, if the estimated impact is precisely zero, or as the case was in our study: the estimated impact was non zero, but not statistically significant. There are several factors, to consider when interpreting null findings, among those are: *what are the expected size of the estimated impact, what are the interventions costs, are the findings consistent with prior research, methodological factors, program implementation and theory of change?.* (203)

First, what is known about **expected size of the estimated impact?** A few studies exist, regarding the typical development of occupational engagement over the time, measured with POES-S, among people with mental illness. The Swedish BEL trial used POES-S to measure occupational engagement in a sample of people with mental illness receiving specialized and community based psychiatric services. The participants in the intervention group (participating in the BEL intervention, in addition to receiving services as usual), had an increase on 2,5 and 3,4 points measured on POES-S at 16 weeks follow up (post intervention assessments) and 6 months follow up, respectively. The participants in the control group (receiving services as usual), had an increase of 0,4 and 1,9 points at the same timepoints. (155)

When the baseline to post-intervention follow-up changes of POES-S in the intervention group and the control group are compared between the BEL results and the post hoc analysis carried out in the MA&R trial, changes in MA&R are slightly smaller with an improvement of 2,55 and 1,45 on POES-S, respectively, than the changes detected in the BEL trial. The interventions offered in the BEL trial might have been more effective than the ones in MA&R on occupational engagement, thus leading to a larger impact on occupational engagement in both groups. Another explanation might be ascribed to the study sample. The mean scores on POES-S, in the BEL trial were based on the participants participating in the

16 weeks and 6 months follow up. The follow up rates were 75% and 66 % in the intervention group at the two time points, and 86% and 75% in the control group. Thus, the mean scores in BEL may be based on a selected sample, namely those completing the interventions. The POES-S scores in the MA&R study were based on all participants included in the study (completers and non-completers).

In a Swedish trial, investigating the effectiveness of supported employment, (SE) among people with severe mental illness, the observer-rated version of POES was used to measure change in occupational engagement among participants, at 6 months and 18 months follow up. Among participants in the SE group, occupational engagement increased from a median score of 28 to 32,5 at six months and to 33 at 18 months follow up, corresponding to an improvement of 5 points over the study period. In the control group, receiving usual vocational services, no change in occupational engagement measured as a median score on POES occurred between baseline and 6 months follow up, but at 18 months follow up, an improvement of about 2 point were found.(206) In the comparison of the POES scores in the three trials (SE, BEL and MA&R) one striking aspect stands out. The median POES score in the SE trial (206) were almost 7 points higher than the mean POES-S score in the BEL study (155) and in the MA&R trial, indicating that the SE participants were more engaged at baseline. Notably in the SE trial, occupational engagement was measured by an observer rated version of POES, not the self-report version POES-S, as in the BEL study and in the MA&R study. This could explain why the POES-S score were similar in the MA&R and BEL studies, but somehow different from the SE study. However, there may be other potential explanations too. Bejerholm and Eklund identified three levels of occupational engagement, measured on POES: 9-18, corresponding to low engagement, 19-27 corresponding to medium occupational engagement and 28-36, corresponding to high occupational engagement. (24) The mean or median scores of participants in all three studies, indicated that they largely remained in their respective categories of occupational engagement, over the study periods. The participants from the MA&R and the BEL studies, remained in the category of medium occupational engagement, while participants in the SE study, remained in the category of high occupational engagement. Medium occupational engagement is according to Bejerholm and Eklund characterized with an even mix of activity peaks, and quiet activities, while high occupational engagement is characterized with occupations being sequential and interwoven. Stimulating environments that provide opportunities for social interactions, self-determination, and anticipation and comprehension for occupational engagement are found in higher levels of occupational engagement. (207) School and workplaces can be such stimulation milieus, with rich opportunities for structured activities and social interactions which may explain why higher scores on POES were seen in the SE study.

Findings from the SE study indicate that an impact of occupational engagement can be expected over a period, similar to the study period in the MA&R trial, however the population in the study, consisted of a group of participants in a interventional context, not completely similar to MA&Rs (e.g. MA&Rs had typically not an affiliation to the labor market and the intervention had a broader scope), hence underlining that a *typical development of occupational engagement* depends on characteristics of the population, other than psychiatric diagnosis, the context and the interventions offered. Based on findings from the SE study (206) and the BEL trial (155), the expectations that MA&R should yield positive findings on occupational engagement did not seem unrealistic, however more research in different samples of the population, in different contexts, in controlled conditions and in different interventional settings, should be conducted, to better illuminate this question.

Another important factor to consider, when interpreting a null finding, is **the intervention`s costs**. Compared to other programs, based on the Lifestyle Redesign® principles, like GN and the BEL intervention, MA&R has a more comprehensive format, since it to a greater extent incorporates one-on one sessions, and offers individual support. MA&R was likely more expensive than BEL but did not produce larger impact on the outcomes. In trials investigating interventions with low costs, null findings may indicate a success, if the results suggest that a less costly intervention may address the health problem as effectively as a more expensive one. In the case of this trial, it is not it likely that MA&R was less costly, due to the format: intervention`s duration, multiple sessions and individual support offered. However, to make more precise estimations of the costs in the intervention group, compared to the control group, information about service use, in respect to standard mental health care, is needed. In this trial, complete information about mental health service use was not collected, which will be discussed in later sections.

In the following, findings are reviewed in relation to their **consistency with prior research**. In mental health, programs based on the Lifestyle redesign ® program are few, so the scope is broadened to look at the effectiveness of these programs, in general, acknowledging that it comes with limitations to compare results across studies with different types of target groups. However, I do find that the principles in Lifestyle Redesign® concern basic human conditions that we all share, regardless of diagnosis, (i.e. occupational needs, and occupational aspects of health), the programs rely on the same mechanisms of change, and are based on the same format: education, mapping own occupations, problem solving, implementation of health promoting behavior, usually delivered in group-based sessions, combined with monthly individual sessions, outings and/or activities (e.g., physical exercises) (208,209), and they all target a population with long term or chronic conditions and often complex needs, which to some extent enable a comparison to be done.

Principles of the Lifestyle Redesign® program have been the foundation of developing similar programs to elderly people in other cultural settings than the US, (n=9), people with chronic pain (n=3), dementia (n=1), stress-related conditions (n=2), mental illness (n=3), stroke (n=1) and diabetes (n=1). (136,154,155,209–226) The programs have been investigated in a variety of study designs, including pilot- and feasibility studies (210,217,221,223,227,228), RCTs (154,155,212,214,229) and qualitative evaluations.(211,218,220,229–231)

Findings from the MA&R trial diverge from the BEL study, who found an effect of the intervention on occupational engagement, measured on 1.4-point between groups difference on POES-S. (155) The results also diverge from the Elderly Well I and II studies, who both found an effect of Lifestyle redesign®, the original program, on outcomes such as role functioning, self-rated health and life satisfaction in the first trial, (136) and bodily pain, vitality and social functioning in the second trial (232). The null findings in the MA&R trial are consistent with findings in two RCTs from UK, investigating the effectiveness of two programs, one targeting elderly people (212) and one targeting people with early stages of dementia, (214) and with results from a Norwegian RCT, (233) conducted with people who had survived stroke. These there RCTs found no significant differences between the intervention group and the control group in outcomes such as quality of life, wellbeing, self-management, activities of daily living (ADL). (212,214,233) Only one RCT, the BEL trial, applied a measure for occupational engagement as one of the outcomes. (155) A Swedish, comparative study investigated the effectiveness of ReDo (Redesigning Daily Occupations) to women with stress related conditions. Findings showed that the participants in the intervention group were more satisfied with their daily occupations and had higher levels of participation, than participants in the control group. (234) There may be a few explanations for why our results both aligns and do not align with results from the other RCTs. One, in the studies concerning individuals with mental health conditions, (155,234), the populations may still be somewhat different. In the BEL study almost half of the participants had children living at home, and in the ReDO trial, around two thirds were living with a partner. In comparison, 80% of the participants in the MA&R sample were single and lived alone. (155,234) No information was given about labor marked affiliation in the BEL group, but in the ReDO study, more than 80% of the participants were working at follow up. (155,220,234) Hence, a consideration is that participants in the BEL study and in the ReDO study, had more opportunities for occupational engagement in their environments (in relation to work, partner, children), than the participants in the MA&R study, and perhaps could better utilize the intervention. Another potential explanation can be attributed to the interventional context. In the RCT by Lund et al, investigating the effectiveness of a Lifestyle Redesign ® adapted program to persons who had survived stroke, the authors ascribed the null findings to the comparator and the context. The program was delivered as an add-on to physical exercise, in senior health centers, where participants from the intervention group and the control group met, had coffee or dinner, and interacted with each other. The authors suggest that "*group interventions focusing on getting out regularly and meeting with peers at senior centers may be as effective as a professionally led program in the long-term rehabilitation after stroke in order to enhance well-being, occupation and social participation."*(233) The interventional contexts in Lund`s study partly resembles the ones in the MA&R study, as the program was evaluated in sites that also offered group interventions, social contact, and/or regular activities. Hence, the null findings in both studies, may be ascribed to similarities in between the intervention and the comparator.

Another possible explanation for the null findings could be the failure of anchoring of MA&R in the context. In the community mental health centers, where most participants were recruited from, and in one of the activity- and support centers, MA&R was delivered by undersigned and a peer-worker employed in our project, and not by regular staff employed at the sites. In comparison, BEL was delivered by staff, employed at the partaking sites. This may have created the opportunities for collaboration with other professionals supporting the participant or talking about contents in the program (for instance, about occupation and health) outside group sessions or after the intervention had ended. However, in the UK RCT, investigating the effectiveness of Journey through Dementia, (JtD) the intervention was delivered in an interventional context, where the many of the participants also received other services. This RCT, showed no effect of JtD, (214) hence integration of the program in the context where it is delivered, cannot fully explain our null findings.

There are several **methodological factors** to consider, when interpretating the results in our study. One important factor is that occupational engagement was only measured twice during a long period of follow-up. Since MA&R builds on both group sessions and an individual session, and a high intensity part (MA&R I) and a low intensity part (MA&R II), it cannot be elucidated whether these components were equally effective or not effective at all. In principle, clarity lacks on whether there is a linear correlation between measuring points, which is a clear limitation when trying to determine a potential cause-effect relationship.

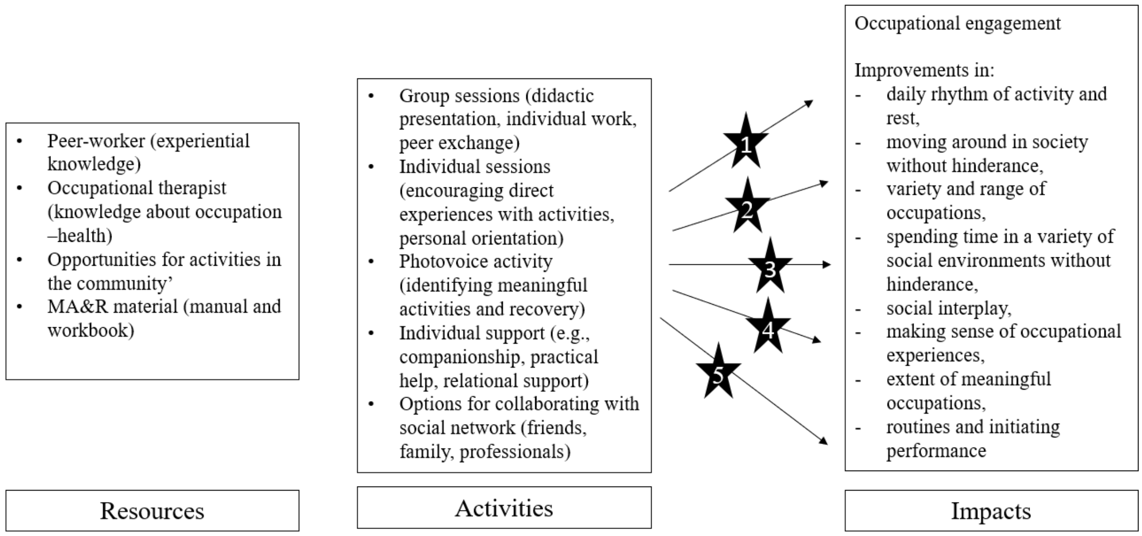
Another methodological factor worth considering, is the outcome measures to measure impact of the intervention. (203) In the study, POES-S was used, to measure change in occupational engagement. POES-S is a time-use instrument that captures the person´s actual doing, in a 24 hours yesterday diary, and the person´s meaning making of doing, reflected in nine items, covering, as described in a previous chapter: "*daily rhythm of activity and rest, moving around in society without hinderance, variety and range of occupations, spending time in a variety of social environments without hinderance, social interplay, making sense of occupational experiences, extent of meaningful occupations, routines and initiating performance."*(149) Looking at the findings from the qualitative study in paper 5, the themes identified in relation to occupational engagement do not accurately correspond to the items in POES-S. Instead, the participants highlighted developing new perspectives on occupations, and a greater appreciation of "the little things", becoming aware of things to do, right at their grasp, and a greater accept of themselves with disabilities. The participants could not identify concrete changes in relation to their daily lives, routines, and ways of doing, it pretty much looked the same as before, but they spoke of sensing everyday life differently, through another "lens" on occupations. Looking at occupational engagement as a continuum of different experiences, as described by Dr. Sutton, (77), one can question whether POES-S was sensitive enough to capture these "micro" changes, described by the participants. The phenomenological study by Dr. Sutton aligns with findings from Bejerholm and Eklund study, identifying phases of disengagement, partly engagement and full engagement, and low, medium, and high levels of occupational engagement, respectively. (24,77) Perhaps there is a need to identify movement not only between these modes, as suggested by Dr. Sutton, but also to broaden our understanding of movement within each of the modes. For instance, in the state of partial engagement, Dr Sutton noted: "*the process of occupation was often more important than the outcome, as simple activity created movement in time and space, allowed expression of self, and opened up other possibilities of being.*" (77) This process aligns with findings from our qualitative study, an aspect of experiencing flow, that was highly valued by the participants. These considerations lead to the discussion of whether there might be distal and proximal outcomes related to occupational engagement. Distal and proximal outcomes measures require perhaps a more fine-grained conceptualization of the occupational engagement continuum, or a more refined program theory. Studies investigating these areas, may have the potential to inform a conceptual framework for understanding change mechanisms in MA&R, and for developing instruments that can capture progress in relation to these change mechanisms. In comparison, the Illness Management and Recovery Scales (IMR-S) were developed to track improvement made by the participants during the program. It was developed in concordance with the program theory and with input from service users and clinicians.(235) An outcome measure, developed by the same principles and methods as IMR-S, might have the potential to measure changes in participants during the attendance in the MA&R program.

An important methodological factor is the "treatment-control contrast". (203) This trial was a pragmatic trial, where the comparator was usual services, as they were delivered as standard mental health care in the partaking sites. Although it may seem conceptually straightforward, identifying the comparator is in many ways challenging. (236) In this trial, the complexity emerged, due to variations in usual care across the partaking sites, that were not only different centers, but also embedded in two distinct sectors: the community mental health centers offering treatment and the activity and support center and the rehabilitation team being municipally mental health services offering rehabilitation. As the sector complimented each other, it was not uncommon that participants recruited from community mental health centers also received services from the municipally and vice versa. Information about actual mental health service use in relation to standard mental health care, was not obtained, because these data were only partly available in the registries. This is methodological limitation, that clearly have an impact on the interpretation of the null findings, for what are MA&R de facto compared to? Information exists, about the usual mental health services offered at the partaking sites, so instead of comparing MA&R to what was done, at least it can be compared it to what was typically done. The treatment-control contrast concerns the recognition that the comparator might be contrafactual and this plays a critical role in the magnitude of effects. Contrafactual raises question to the actual differences in the intervention group and the control group and whether the service contrast was strong. (203) In MA&R it was anticipated that the impact on occupational engagement, would be driven by formal and informal peer-support, individual support and knowledge about the health-occupation relationship and direct experiences with activities. Scrutinizing the services offered at the partaking sites, there are some similarities between the core components in MA&R and the usual mental health services. One, the community mental health centers and two of the three activity support centers had employed peer-workers, hence many participants in both study arms had access to formal peer-support. Two, participants had access to informal peer-support, either in groups led by peer-workers or clinicians in the community mental health centers and the rehabilitation team, or in the various services offered in the activity and support center. Three, direct experiences with activities were offered in the activity-and support centers (e.g., sport, creative activities). Fourth, information about the health-occupation relationship was available to a least some of the participants, as occupational therapists were part of the staff in the partaking sites. However, there were also differences. One was the intensive focus on occupations in relation to health, wellbeing, and recovery. Two, in MA&R there was a more individually tailored approach, offering individual support to engage in activities in the community and following each group session up with a one-on one meeting. Three, activity opportunities in MA&R were not limited to what where available in the site, but also encompassed activities in the wider community, such as travelling to Madeira and joining a Stand-Up Paddle board community. Hence, although the treatment-control contrast, in our trial is blurry, it is reasonable to assume that there were both differences and similarities between the study groups, in aspects likely to drive the impacts, although the services might have not differed as substantially as we expected when we designed the study. Hence, this methodological factor is important for the interpretation of the null findings, in the trial.

The null findings in this trial, may also be attributed to **program implementation**, and to what extent, the essential elements of the MA&R was delivered consistently. Fidelity reports showed that the MA&R intervention, was delivered with good to optimal fidelity at all sites. However, the impact of the COVID 19 lockdown and restrictions had consequences for the implementation of MA&R, that could not be foreseen when developing the MA&R fidelity scale in 2018. The most significant consequence was that many of the activities in the community were restricted, which drastically narrowed down the opportunities for occupational engagement during the trial. Thus, COVID-19 pandemic had a crucial impact on the context in which MA&R was delivered, and this might explain the null findings in the RCT. It can be discussed whether the trial should be postponed, and be continued after the pandemic, but on the other hand, we did not know how long the restrictions would last for, and possibly, we did not fully comprehend the consequences of the restrictions, in relation of MA&R. The COVID 19 also affected another aspect of the delivery of MA&R, namely the number of participants in the group sessions. Due to distancing, only four to five participants were allowed in the MA&R groups (n=3) that started after March 2020. Participants were instructed not to attend group sessions, if they had a cough, or had minor symptoms of a cold etc. The size of the groups, together with an increased number of cancellations from participants, limited the range of informal peer-support, as it became common that only one or two participants were present at the group sessions. This was addressed in the qualitative study of MA&R, where participants stated that too little things in common with fellow participants in the group sessions was a barrier for engaging in MA&R. Only 40 of the 67 participants who started in a MA&R said yes to individual support, one of the core components in the intervention. They had in average 2,8 encounters with the occupational therapist and the peer-worker. The amount of individual support offered was less than excepted and one can discuss whether it was sufficient to enable meaningful engagement. All participants were offered individual support; however, some declined or cancelled on the day. Also, due to restrictions during COVID 19, some participants who had received support before the lockdown, were not interested in continuing with it, as the activities they had been engaging in, were closed. Receiving individual support may be an ambiguous experience. In a study of an occupational therapy intervention to enable occupational engagement, participants reported that engaging in the intervention was rewarding, and at the same time demanding. The participants valued the collaboration with the occupational therapist, where they worked together with the purpose of engaging in occupations, prioritized by the participants. However, they also found that the process of re-engaging in occupations confronting, and requiring energy, determination and time. (237)

Although MA&R consists of multiple core elements and deploys a mix of group sessions, individual sessions, and individual support to engage in activities, a central feature of MA&R is that there are no stated definitions of a therapeutical dose, so to say, no lower thresholds for attendance, for expecting an impact of the intervention. For instance, some participants only had one-on one session with an occupational therapist, thus not being exposed to peer-support, a critical core component in MA&R. Others participated in the planned sessions but did not receive individual support, and so on. The mean attendance rate in MA&R was about 68%, corresponding to 15 out of 22 possible sessions. Determining the dosage-efficacy in mixed interventions with multiple components such as MA&R, and Lifestyle Redesign® is not an easy task. In an analysis of participants from the Elderly Well study II, (232) that took part in individual sessions and/or group sessions and/or outings in the community, the findings showed no evidence for a doses-response effect for any of the intervention modes, or for an interaction between the individual sessions or any of the two other modes, or an threshold effect, for any of the modes. (238) To sum up, program implementation failure cannot be ruled out as an explanation the null findings. However, this should firstly be attributed to continuing the trial during the pandemic, and to lesser extent delivery of all modes in MA&R to every participant, as a flexible approach and person-orientation was a key feature, and knowledge about the dosage-response relationship is lacking.

Finally, and importantly, the null findings in the RCT, may be a result of **flaws in the theory of change**, from which MA&R was developed. As described, MA&R was informed by stipulated change mechanisms in the Lifestyle Redesign® program (136) and from the qualitative synthesis of transfer. (142) An overview of the anticipated change mechanisms in MA&R and their relationship to occupational engagement, is provided in a simplified logic model in figure 9. Following the qualitative evaluation of MA&R, and a comparison these findings with qualitative evaluations of BEL (231) and the occupation focused program, Action over Inertia (AOI) (226), some themes have emerged that propose change mechanisms that were not considered when developing the initial program theory.



Anticipated change mechanisms:
1. Gaining greater knowledge about occupation-health would enable participants to re-order their occupations into healthy, stable patterns,
2. Delivering sessions in a safe, respectful mode will inspire participants to reflect upon occupation, practice social skills and build confidence.
3. Drawing on experiential knowledge will enhance the process of transfer from group sessions to everyday life.
4. Engaging in meaningful activities have positive spill over effects.
5. Individual support can help the participants in engaging in activities in the community.

Figure 9: An overview of the initial program theory, informing the MA&R trial, depicted as a logic model.

A prominent finding in the qualitative study, was that participants during MA&R adopted new perspectives on everyday life. Participants increased their awareness of occupations that were meaningful, that promoted wellbeing and that were right at their grasp. This altered perspective on occupations opened a broader range of opportunities for feeling immersed, getting in the state of flow, for daring to take a change and try new things, and for becoming less self-critical when performing activities. Participants experienced recovery being embedded in the ordinariness of their everyday lives, in their homes and near surroundings, and in the appreciation of the mundane and little things often taken for granted.

The findings of the qualitative study correspond with findings in the AOI study, in which participants identified meaningful activities, experiencing the advantages of doing a little more, and engaging in ways that gave them a sense of hope, as significant effects. (226) Participants in MA&R also changed how they thought about themselves in connection to what they were doing, softening a previously black-or-white view of themselves and expanded their personal toolbox for recovery with accessible activities (for instance, lying on the coach with one`s pet). Seeing oneself trough an altered lens, aligns with findings from the qualitative study of BEL (231), where coming to terms with oneself, by going on things gently, was a way of breaking the cycle of perceived failure. (231) The findings from the qualitative study indicate that changing <u>perceptions and perspectives</u> are main effects of MA&R, and subsequently might lead to change in doing, if change is broken down into small, achievable steps. Developing a new lens on everyday activities might be facilitated by multiple sources. Firstly, information about occupations, how they take on different forms, function and meanings, and the occupation-health relationship, for instantly explained through flow. Secondly, the process of participants “experimenting” with occupational experiences, e.g., exploring how these could have “catalyzing” effects, bringing joy and immersion. Thirdly, feeling **seen,** which seem equally important to feeling supported. This may be promoted through the personal postcard that the participants were received, and the peer-workers` and occupational therapists’ authentic tone. Fourth, the individual approach, endorsed through for instance one on one sessions or individual support, which was highly valued among the participants, and compared to having a personal trainer for occupations. Whether or how these change mechanisms and their impacts relate to occupational engagement is not clearly stated. Perhaps they are predictors, or indicators for movement in the continuum of occupational engagement, however, more research should be conducted in this area. How the focus in MA&R on meaningfulness in engagement facilitate occupational engagement and opportunities for recovery should be further investigated, and have the potential to inform further development of program theory (111). For now, findings from the evaluation of MA&R, are translated into a new logic model, proposing a revised theory of change, as seen in figure 10.

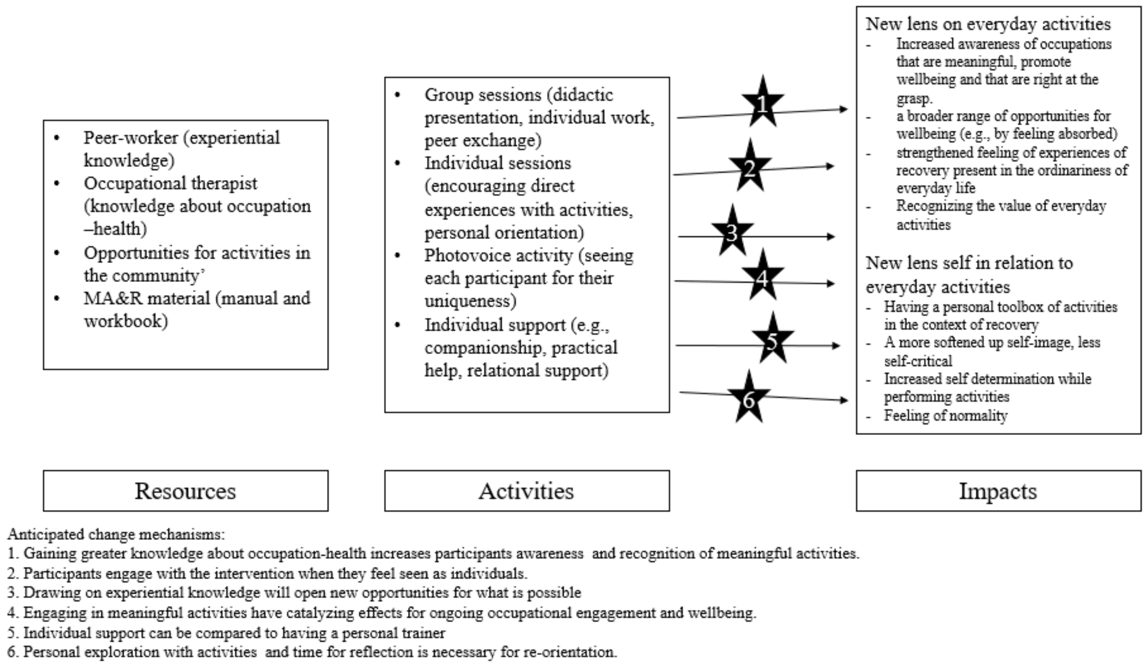


Figure 10: an updated logic model, proposing change mechanisms in MA&R, based on findings from the qualitative study.

5.4 Methodological considerations

In this section, methodological limitations in relation to the study design and methods, regarding the quantitative synthesis on transfer (142), the RCT investigating the effectiveness of MA&R (154) and the qualitative study of participants experiences of occupational engagement in relation to MA&R, will be discussed.

5.4.1 The qualitative synthesis on transfer

In this section, the methodological limitations in performing secondary analysis, is dwelled upon. (145,239,240) Using existing datasets to answer new research questions, as it was done in the qualitative synthesis, comes with a range of possibilities but also pitfalls. Hinds (240) argues that datasets must be carefully inspected, to deem if they are amenable to secondary analysis. To what extent do the research question differ from the original research question, and do the phenomena of interest occur in the transcripts, to an extent that allows it to be accurately studied? (240) Recovery was the phenomena of interest in the original studies, which is a broader topic than transfer. Furthermore, the interviews were focused on how the participant experienced an intervention, (IPS, IMR) in relation to recovery, while the links (and gaps) from the intervention to everyday life in the community, was the matter of interest in the qualitative synthesis. One can ask whether the interviews contained enough information and "thick descriptions" to allow the research question posed in the qualitative synthesis, to be answered. According to the interview transcripts, the interviewer asked questions like "Has participating in IMR altered anything for you? " and "Did you learn anything during IMR, that you could use? " In transcripts where information about transfer were missing, it did not simply mean that the topic of interest was not touched upon in the original study. An interpretation in the analysis, was that participants had difficulties in pointing out how they could transfer what they learned during the group sessions, to the wider life. A major limitation of conducting secondary analysis, is the distance to the data. Qualitative data are generated and through interactions between researchers and participants. The original researchers Sofie Bratbjerg Jensen and Iben Gammeltoft Nielsen who conducted the interviews in the original studies (143,144), generously shared their field notes, with personal and detailed memos about the context (e.g., descriptions of the place, time of day, interactions before and after the interviews etc.), and non-verbal communications during the interview (e.g., sighs, laughter). However, the sound-files were not available, neither was tacit information situated in the interview situation, such as tensions, atmospheres, surroundings etc. This may have hampered the analysis, and increased the risk for misinterpretation or overlooking important points made by the participant. (145,240) Another major limitation in secondary analysis, are the lack of possibility of engaging in dialogue with participant about topics one finds interesting for further exploration. When reading the transcripts, it is not possible to go back and ask the participants for clarification of or elaboration on statements. Again, this increases the risk for misinterpretation and for missing out on "thick descriptions" on the matter of interests, in this case transfer. Finally, a third limitation is the lack of possibility for recruiting until saturation is completed. Hence, secondary analysis requires relatively large datasets. (239)The datasets in the qualitative synthesis consisted of a total of 39 interviews, from four different psychosocial interventions. Given the variation of participants in relation to life conditions, diagnosis, age, and intervention type, one can question whether data saturation was acquired in our study. Most likely, including more participants, would have yielded more nuanced descriptions to the transfer process.

5.4.2 The Randomised controlled trial

Although the RCT investigating the effectiveness of MA&R, followed the CONSORT statement (121) and the SPIRIT guidelines for defining protocol items in clinical trials (241), thus enhancing the trial`s rigor and strengths, the study design also had limitations, which increased in risk of bias, and thus must be taken into account, when interpreting the findings. One, neither the participants nor the staff delivering the intervention were blinded to intervention assignment. The occupational therapist who developed MA&R (the author) also delivered the intervention in some of the partaking sites. Expectation bias happen when staff`s or participants` expectation about certain outcomes influence the perceptions of their own and others performance.(242) As a consequence, staff believing in the intervention, may have behaved differently, for instance bringing more enthusiasm into the sessions, or being more assertive or flexible. Hence, the effectiveness of MA&R, would then not only be attributed to the program, but also to the staff delivering it. Furthermore, for participants in the intervention group, awareness about and expectation to the experimental intervention, could have affected their adherence and engagement in MA&R. Participants` expectations also could have inflated their ratings while answering the questionnaires at post intervention follow up. This may have potentially induced a bias in the results, causing the differences between the groups seem higher, than they really were. Attempts were made, to address this risk, while recruiting participants, stressing that the MA&R intervention was experimental, and it was not known whether it was better than the interventions already existing. However, participants who consented to be included in the trial, often did so because they found the methods described in the intervention, appealing. A better way to address this, would be to conceal the research hypothesis to staff and participants, and to introduce an active comparator in the control group, that did not have any relation to the outcome (e.g., a psychoeducational online program). Another source of bias is the observer/interviewer bias. Some participants received assistance in filling out the questionnaires prior to randomization (baseline) and at post intervention follow up. The participants who received help, were instructed to not reveal their allocation group to the research assistant, to prevent the research assistant expectations influencing (consciously or unconsciously) the participants self-ratings. (242,243) A record was kept, to register occasions where the research assistant was unblinded. Most often, this happened when a participant refused to take part in the follow up assessment. Of the participants providing information in the post intervention follow up, the research assistant was unblinded in 3 cases, all being in the control group.

An important methodological limitation to address, concerns the registration of the participants` service use, in respect to usual mental health care. As MA&R was tested as an add-on, most participants in both groups received services from the community mental health centers and/or the municipality services simultaneity. However, there were great variations among participants regarding the extent and type of service use. MA&R was evaluated in a multi-center trial and some sites registered their services (e.g., the community mental health centers) while others did not (the activity and support centers). We decided not to collect this data from the registries as they would yield incomplete information about service use among the participants. As an alternative to registry-based data, we could have added questions about service use to the self-report questionnaire at post-intervention assessments. The lack of information about service use in both groups is a limitation. Consequently, we do not know whether the intervention group and the control group are equally balanced, in respect to prognostic factors related to the interventions, that is expected to have an impact on the outcome, and whether the missing effects of MA&R can be attributed to similarities between the intervention and services in the control intervention as previously discussed. Recording service use, during the trial would certainly clarify this question.

5.4.3 The qualitative evaluation of MA&R

There are some methodological limitations that need to be accounted for, when it comes to the trustworthiness of the findings in the qualitive study on participants experiences with occupational engagement in relation to MA&R. Credibility refers to the extent of which findings represents the relevant information drawn from the participants` data, and whether the findings reflect correct interpretations of the participants perspectives and views. (244) Credibility can be reinforced by triangulation, which involves the use of multiple methods, investigators and/or theories to reduce systematic bias and bring multiple perceptions in to the investigations and hereby strengthen the quality of the findings. (244–246) In the qualitative study, there were three researchers (NKT, JRC and undersigned) who frequently met, to discuss and share our growing insights into the phenomena. This occurred especially during the analysis and interpretation of findings. However, the triangulation was limited by the fact that all three researchers shared similar backgrounds, all being occupational therapist with various degree of professional experiences. Hence, the analytical lens and theoretical underpinning were informed by an occupational perspective on health and by a joint conceptual understanding of occupational engagement. Involving researchers with different professional backgrounds and/or with lived experiences with mental illness, in the study, would have added new perceptions to the phenomena and thereby consolidating the findings. Triangulation also concerns applying different research methods for a more comprehensive understanding. Since the study concerned occupational engagement in relation to MA&R and recovery in the context of daily life, participants observation would have added important knowledge, about how participants experienced MA&R and how it related to their everyday life outside the interventional context. Furthermore, taking on a longitudinal approach, with multiple interviews over time, could have provided valuable nuances in the insights into the development of occupational engagement over time, and in relation to different stages of recovery.

Transferability concerns the degree the findings can be transferred to other contexts and settings with other respondents. Transferability is enhanced trough "thick descriptions" of methods applied and this was thoroughly done in the Master thesis, written by NKT. Therefore, a methodological factor associated with transferability, namely sampling strategy will be discussed here. Eligible informants in a qualitative study are those who posit knowledge about the issue being investigated. They are not selected for generalizability. Instead, participants are recruited by the "saturation criteria", that is to ensure enough information to develop valid understandings of a phenomena, and no additional data will expand the understanding, e.g. contributing to new codes or themes. (247) Whether the findings in this study cover all experiences people had with occupational engagement during MA&R is highly unlikely. Hence there are limitations for to which extent our findings can be transferred to other contexts and populations. One, the participants mainly consisted of participants who had completed MA&R. This may perhaps have contributed to an overweight of positive experiences with MA&R, in the findings. If the attempts to recruit participants who had discontinued MA&R would have succeeded, it would have probably yielded more nuanced results, that potentially could be transferred to a broader range of respondents and added important perspectives in interpretation of findings from the trial. Moreover, the study sample consisted predominantly of men. This may have impacted the experiences of MA&R; however, it was not reflected in the interviews with the participants. Distinct patterns in occupational engagement, based on gender could not be established in the interviews. Even though the impact is unclear, the transferability of our findings may be restricted due to an overrepresentation of men in the study sample. (123,244)

6. Conclusion

6.1. Main findings

The overall goal with this thesis, was to inform occupational therapists and peer-workers employed in mental health services, how they jointly could support people with psychiatric disabilities in engaging in meaningful occupations. This thesis describes the development and the evaluation of the MA&R intervention. The development of MA&R was informed by already existing and evidence-based interventions, the IMR program, the IPS model and peer-support, and on learning theories on transfer. The interventions were scrutinized separately, and compared across, for their ability to enable and support people to pursue recovery goals and engage in activities in everyday life in the community. It was anticipated that extracting the active ingredients from each of the interventions, and "packing" them together with key principles from Lifestyle Redesign ®, MA&R would facilitate occupational engagement, and promote personal recovery, quality of life and functioning. MA&R was evaluated in a pragmatic RCT open for wide inclusion in mental care services, where it was hypothesized that MA&R when offered as an add-on to usual mental health care would be better than standard mental health care alone, and the difference between the groups would correspond to a moderate effect size. The findings from the RCT did not confirm this hypothesis, as they showed that MA&R was not superior to the mental health services already being offered, when it comes to enabling occupational engagement, or in any of the other's outcomes. Flaws in the research design impede us from drawing conclusions about whether the null findings can be ascribed to the fact that the treatment-comparator contrast was smaller than anticipated. Comparing what was offered in usual mental health care and what was key ingredients in MA&R, there were several similarities. However, as we did not register services use among the participants, limited interferences can be drawn, in respect to similarities and differences, in the two study groups.

Nevertheless, one thing that made MA&R unique, compared to standard mental health care was the opportunities for individual support, to transfer and engage in activities by choice in the community. This opportunity was partly hampered, due to the COVID 19 lockdown in March 2020. The post hoc analysis suggested that MA&R might have been better (thus worked differently) before the pandemic and under "normal conditions", but during the COVID 19 the conditions for occupational engagement were severely restricted (concrete, mentally and socially), leading MA&R to be no better than the existing mental health services. Besides from the unexpected event of COVID 19, MA&R was delivered with good to optimal fidelity in various mental health settings and with high acceptance and adherence rate during seven months of combined intervention. This indicates that although MA&R is not more effective than what usual mental health care, it is an acceptable and implementable intervention, that demonstrate that a peer-occupational therapist collaboration not only is feasible, but also make good sense.

Combining results from the qualitative evaluation of MA&R with findings from the RCT, introduces the possibility of theory failure, flaws in the anticipations about change mechanisms. Together, the RCT and the qualitative study might indicate that core mechanisms in MA&R did not change doing. Instead, some of the intervention elements may have affected other aspects of occupations related to meaning making, savoring and presence and that these phenomena, yet not well described, are relevant aspects of the recovery process. Looking at within group changes on POES-S item level, we found that both groups had small, significant improvements in daily rhythm of activity and rest, extent of meaningful occupations, routines and initiating performance. Only participants in MA&R had significant improvements in making sense of occupational experiences. The findings do somewhat align with findings from the qualitative study, and may provide insights into the potential change mechanisms in MA&R, as suggested in the revised logic model, gaining new perspectives on self and everyday life activities as a novel outcome, unique to MA&R. Since MA&R introduced a unique focus on engagement and meaningfulness, and seemed to be as effective as existing interventions, it has the potential to be further developed. It's possible that MA&R will facilitate engagement processes and recovery opportunities, but more research is needed in this area. A key element of MA&R was peer support, which will be taken into consideration in future research on co-productions to enhance MA&R delivery and impacts

6.2. Implications for practice

This thesis has shown that including occupational engagement as a recovery goal is important to people with psychiatric disabilities, and therefore a relevant target to address, for occupational therapists and peer-workers employed in mental health services. Combining experiential knowledge with an occupational perspective on health allowed the occupational therapists, together with the peer-workers, to go beyond a professional and patient/service-user dualism and discuss occupations as common experiences where there were no rights or wrongs and acknowledge that occupations were meaningful in their own being. Delivering peer-co led interventions focused on occupational engagement, may strengthen the humanity (and user relevance) in mental health services. Such interventions may not only impact the lives of people with psychiatric disabilities, but they might also transform the professional lens of those delivering them.

Findings from the qualitive synthesis suggest that interventions delivered in institutional settings may be beneficial for supporting personal growth, but also have their limitations when it comes to strengthen occupational engagement in the community. Accordingly, I recommend peer-workers and occupational therapists, but also health policy makers, to be careful, not overestimating the impact and transferal speed of for instance group-based or office-based interventions, on participating in everyday activities. Based on the null- results from the RCT, we cannot recommend MA&R being implemented in its current format. However, the MA&R was not associated with any harms, and post hoc analysis showed that participants from both study groups improved significantly over time, in several of the outcomes. One can say that MA&R worked just as well as many of the other mental health services that are offered to people with psychiatric disabilities. The attendance rate in MA&R and findings from the qualitative study, indicated that the interventions format, combining group and individual sessions and support, was acceptable and enabled a personal orientation that was highly valued among the participants. I argue that this is a unique combination, that fits well with recovery-orientation, and a tool for tailoring mental health services to match the individual`s needs and preferences. Adding individual sessions should be considered when delivering other group-based services too. Findings from the qualitative study showed how experiences of recovery and occupational engagement are connected and embedded in everyday life experiences. Watering plants, brewing a good cup of coffee in the morning are small and mundane activities, that are often taken for granted (and may not be captured by patient reported assessment tools like e.g., POES). Mental health professionals have a high workload and are often expected to handle multiple and often complex needs. They may easily overlook small glimpses of recovery in the daily life context. We hope that the qualitative study on occupational engagement can encourage mental health professionals, to be attentive to the ordinariness of everyday life, to acknowledge that small silver linings matter too, in the bigger picture, and things not always need to be grand to be good. This should not at least be clarified when determine relevant achievable outcomes in randomised controlled intervention trials as MA&R.

6.3 Perspectives for future research

Following the results from the evaluation of MA&R, several research questions are relevant to address. As proposed in the MRC Framework, both context, program theory, stakeholder perspectives, key uncertainties intervention refinement, comparative resources and outcomes consequences, should be considered. (112) As was stated in the preceding chapter, the unexpected event of COVID 19 altered the context, and potentially hampered the mechanisms of change in MA&R. Hence, MA&R should be evaluated again under "normal conditions". Future trials should register mental health services use, in addition to MA&R, to obtain better insights into the comparator. However, before undertaking a new evaluation, intervention refinement must be considered. There might have been aspects with MA&R not working sufficiently to impact occupational engagement. Among those aspects is the question of how the social environment, (e.g., making connections between participants, collaborating with significant members of the participants` social network, prolonged individual support) can be utilized for better support occupational engagement and how MA&R can encompass a more nuanced understanding of occupations. There might also be other aspects of MA&R, which has not been touched upon, that might be relevant to address. A refinement of MA&R requires involvement and close collaborations and co-productions with relevant stakeholders: people with psychiatric disabilities, significant members of their social networks and professionals. Furthermore MA&R`s program theory needs to be revised, as proposed in the previous chapter.

In addition to research areas concerning the development and evaluation of MA&R, key uncertainty resolves around the process of occupational engagement. I suggest that there are at least three research questions that need further research:

1. How is movement on the occupational engagement continuum enabled and experienced by people with psychiatric disabilities in various stages of recovery?

2. How do environmental and occupational factors impede or facilitate occupational engagement?

3. How can occupational engagement be promoted in recovery-oriented systems of care

1. How is movement on the occupational engagement continuum enabled and experienced by people with psychiatric disabilities in various stages of recovery?

Addressing the lack of freedom to move between different modes of engagement is important, when understanding occupational engagement.(77) It also is critical to gain deeper insights into how occupational engagement evolves in different stages of recovery. It has been proposed that the recovery process can be understood as unfolding over distinct stages, for instance *moratorium* characterized by sense of loss, withdrawal, and hopelessness, *awareness:* hope and realization that a fulfilling life is possible. *preparation*:

taking stock of strengths and weaknesses, *rebuilding*: actively working towards recovery goals and *growth:* living a full and meaningful life. (248) Although the stages are clearly simplified, they point out that recovery means different things to different people, at different timepoints of their lives. This was also found in a study by Yarborough and colleagues, showing that recovery was perceived as coping and having basic needs met (getting by), learning to live the mental illness (getting back) and living a life not marked by mental illness (getting on). Results showed that people may have low expectations for recovery, while others were focused on self-care and coping for achieving higher ordered recovery goals or believed in recovery as a reaching point where they could get on with their lives. (16) Limited knowledge exists on how occupational engagement are enabled in these different stages, for instance, when one sees no hope for recovery. Perhaps self-reflection and inspiration are important for initiating a movement or having opportunities for trial and error in safe and affirming environments. Professor Strauss identified "Woodshedding" as the first critical path on recovery. "Woodshedding" may look like a standstill, that the individual has reach a plateau, where no further progress happens. The phase may be long and frustrating and requires patience and constant encouragement. Professor Strauss stated that "Woodshedding" is a regulatory mechanism and a timing arrangement so the person can gain stamina and surplus, needed to face the next major change towards recovery.(92,249) The process of recovery, is non-linear, dynamic and changes over time, and so is occupational engagement. The phenomena can be investigated by narrative interviews, as in the study by Sutton et al (77) or in a qualitative longitudinal study with repeated interviews, similar to the one conducted by Strauss. (92) Understanding how the continuum of occupational engagement is experienced in various stages of recovery holds potential for articulating more sophisticated models for occupational engagement, that can inform the development and designed of future mental health services and help occupational therapists and peer-workers accommodate their practices to be more person-centered, flexible, and responsive.

2. How do environmental and occupational factors impede or facilitate occupational engagement?

Occupational engagement can be understood as a "loop" where the individual`s interpretation of their doing (perceived value, positive and negative consequences) and the feedback they receive from the environment, over time impact the individual`s participation in activities. (62) Consequently occupation focused interventions include educational approaches with opportunities for personal explorations. (136,154,155,225) However there is need a broaden the scope, and to a obtain more knowledge on obstacles and opportunities for occupational engagement embedded in the environment and the occupation itself. A qualitative study investigated barriers and enablers to participate in cultural and community activities among people with mental health conditions. Findings showed that although participants were motivated to participate for several reasons, e.g., cultural identities, increased wellbeing, or the desire to make new connections and friendships, opportunities for engagement were sometimes hampered by the costs, transportation inaccessibility, the unstructured nature of activities, or social anxiety associated with attending. The authors suggest some potential ways to encounter the obstacles, such as long term, sustainable funding for covering expenses and arranging appropriate transportation, or collaboration with community organizations to provide welcoming environments. (250) This study takes on an important perspective in investigating how occupational engagement can be impeded by factors outside the individual and identifies an import area for future research. This can be studied, for instance in an action research design. Action research, also called participatory research is according to O`Brian, characterized by its dual commitment to study a system, and concurrently collaborate with members of that system in changing it in what is together regarded as a desirable direction, thus stressing co-learning as an important part of the process. (251,252) Hence, engaging in partnerships with people with psychiatric disabilities, for investigating obstacles and opportunities for occupational engagement in the community, in a process of collecting data, analyzing it, and determination actions in an iterative cycle may be an appropriate and useful method to produce valuable knowledge about environmental determinants for occupational engagement.(251)

3. How can occupational engagement be promoted in recovery-oriented systems of care

Moving beyond an individualistic perspective on occupational engagement and recovery, it is critical to investigate how mental health professionals, including occupational therapists and peer-workers can collaborate across systems and sectors to strengthen community participation and inclusion. In a historical review of recovery-oriented systems of care from 2022, Davidson and colleagues state that the field has not be empirically evaluated, so far. “Recovering citizenship” has been proposed as a possible direction for recovery-oriented systems.(253) Citizenship is a person’s connection to rights, responsibilities, roles, resources and relationships, also referred to as the 5 Rs. Society makes the 5 Rs available to its members through social and public institutions, along with a sense of belonging to the community, trough validation by others. Overall, there are two pathways to citizenships: one, the individual efforts and support to gain access to full citizenships, two, the society`s responsibility to open up access to citizenships.(254) For professionals working in mental health services, recovering citizenship would involve engaging in new partnerships across sectors, and public and social organizations. For occupational therapists and peer-workers employed in mental health services, this could include collaborating with libraries, sports clubs, NGOs, clubhouses and so forth, to enable occupational engagement, for people with psychiatric disabilities, within a broad range of everyday activities, for instance social hubs, education, civic life, cultural activities, or artistic pursuit. How to work collaboratively with various institutions and organizations in the community, is an important research area, that must be targeted from multiple angles, including investigating shifts in culture, both in mental health services, but also in society, developing paths from mental health services to broader community life, and vice versa, and designing environments that are perceived as welcoming and accepting by people with psychiatric disabilities.

7. Summaries

7.1. English summary

Background: Mental illnesses affect an increasing number of the population, often with severe consequences for people`s everyday lives. Isolation, loneliness, and a sense that life has come to a standstill can be caused by symptoms as well as environmental factors such negative attitudes towards mental illness. Everyday activities are fundamental for health and wellbeing, and provide opportunities for connections, daily structure and for becoming aware of and sustain one´s capacities. Occupational therapists in mental health aim to enable people to participate in everyday life activities, in the presence of challenges imposed by the illness. Collaboration with peer-workers is proposed as a method that make good sense and holds potential for being an important contribution to the work of enabling occupational engagement. So far, there is limited scientific evidence on how such collaboration can be implemented and whether occupational therapy interventions for people with mental illnesses are effective.

Objective: To develop and evaluate Meaningful Activities and Recovery (MA&R), a peer co-led occupational therapy intervention, developed to promote knowledge about how well-being and mental health link to meaningful activities, and to provide opportunities to explore and incorporate activities in line with the individual's unique characteristics, experiences, competences, interests, and values.

Methods: A scoping review was conducted prior to the development of MA&R, to identify and assess the available evidence for occupational therapy in mental health. The principles of the Lifestyle Redesign ® program, an occupation-oriented, group-based intervention for older people that has demonstrated its effectiveness in two randomized trials, was adapted to the target group in this study. The further development of MA&R was based on transfer theories, and a qualitative synthesis of participant`s experiences of Illness Management and Recovery, (IMR) Individual Placement and Support, (IPS) Learn to Tackle Anxiety and Depression, (LTAD) and Turning Points, the two latter are programs led by people with lived experiences of mental illness (peer-workers). The qualitative synthesis informed the development of MA&R, where peer support (in group and by peer employee) and individual support, along with a focus on meaningful activities, were identified as core components. MA&R was evaluated in a multicenter, pragmatic randomized trial. The research hypothesis was that MA&R, in addition to with standard mental health care, would be better in terms of increasing engagement in meaningful activities (occupational engagement), and improving quality of life, functional ability, and personal recovery. Participants were randomized 1:1, to either 1) MA&R in addition to the standard mental health or 2) the standard mental health care. Data were collected twice, using questionnaires. The timepoints were at baseline before randomization and at post intervention follow up. (When MA&R ended) In order to investigate how participants perceived occupational engagement during MA&R, a qualitative study was conducted, consisting of semi-structured individual interviews and thematic analysis.

Results: In the scoping review of existing evidence, published between 2003 and 2018, 21 original studies and 3 systematic reviews were identified. There was considerable variation among the studies in relation to target group, context, type of intervention and study design. Individualized interventions, group sessions showed promising effects in relation to functioning and occupational engagement. The scoping review showed that there were few studies of high methodological quality evaluating the effectiveness of occupational therapy interventions. The qualitative synthesis found that through engaging in group discussions in IMR, Vendepunkter and LTAD, the participants improved self-confidence and presence in social situations, and that this could be transferred to better quality in interactions with friends and family, and more assertive communication with professionals. Results also suggested that mirroring oneself in the experiences of peer-workers (In Vendepunkter and LTAD), the participants developed self-care strategies that could be transferred to situations in everyday life. The group-based formats had their limitations in terms of being able to transfer what was learned during sessions, into everyday activities in the broader perspective. Individual support, as it was experienced by IPS participants, could somewhat address these limitations if the support was perceived as flexible, authentic, and timely. In the randomized controlled trial 139 participants were included between 2018 and 2020, randomized either to 1) MA&R + standard mental health care (n=70) or standard mental health care alone (n=69) A total of 10 MA&R groups were completed, in community mental health centers, activity and social support centers and a rehabilitation team, at Mental Health Center Copenhagen, and the municipalities of Svendborg, Odense and Copenhagen. Participants' mean age was about 43, about 50 % of them were men. Most were single, lived alone, did not have children, and received early retirement or unemployment benefits. About 82% of the participants completed MA&R. On average, they attended around 15 out of 22 scheduled sessions. At follow-up, there were no significant differences between the intervention group and the control group in occupational engagement, functioning, quality of life and personal recovery. Post hoc analyses showed that both groups had significant improvements in several of the outcomes, and that MA&R may have been better than the standard mental health care, before COVID 19, but not during. Interviews with participants from MA&R (n=13), described the intervention as a practical approach to recovery, with opportunities for re-orientation, on meaning-making in the seemingly mundane and new perspectives of everyday life, on one`s own terms.

Conclusion: MA&R was no better than the standard mental health care when it came to increasing occupational engagement, or improving functioning, quality of life, or personal recovery. Based on this, we cannot recommend implementing MA&R in its current form. The lack of effects may be due to the contrast between MA&R and the comparator being overestimated, or that the trial was partially conducted during COVID 19, which may have hampered the opportunities of occupational engagement, thus affecting anticipated mechanisms of change. Participants` experiences indicate that MA&R can first and foremost support new perspectives on everyday activities, as well as facilitate a sense of quality and meaning making when engaging in occupations. This may be important for occupational engagement and recovery in the bigger picture, did but not directly lead to concrete and tangible changes in everyday life.

7.2. Dansk resume

Baggrund: Psykiske sygdomme rammer et stigende antal mennesker, og har ofte svære konsekvenser for deres liv og hverdag. Både symptomer fra sygdommen, men også forhold i omgivelserne som negative holdninger til psykisk sygdom, kan føre til isolation, ensomhed og en følelse af at livet er gået i stå.

At have noget at stå op til, hvor man bruger af sig selv, og er en del af et fællesskab hvor man er værdsat, er grundlæggende for alle menneskers sundhed og trivsel. Ergoterapeuter i psykiatrien arbejder for at gøre hverdagsaktiviteter mulige og at livet kan leves, selv med de udfordringer som sygdommen og dens konsekvenser medfører. Ergoterapeuter bidrager med indsatser hvor formålet er at skabe mere deltagelse i hverdagsaktiviteter, der er meningsfulde for det enkelte menneske. Samarbejde med peer-medarbejdere er foreslået som metode, der kan give god mening og være et vigtigt bidrag ind i arbejde med at muliggøre meningsfuld aktivitetsdeltagelse. Foreløbigt er der få videnskabelige studier der belyser hvordan samarbejdet kan udmøntes og om ergoterapeutiske interventioner til mennesker med psykiske sygdomme har en effekt.

Formål: At udvikle og evaluere et nyt tilbud, Meningsfulde Aktiviteter og Recovery (MA&R), som faciliteres af en ergoterapeut og peer-medarbejder. I MA&R er der fokus på at formidle viden om hvordan trivsel og mental sundhed næres gennem aktiviteter, der er meningsfulde og at give muligheder for at udforske og indarbejde aktiviteter, der harmonerer med den enkeltes unikke egenskaber, erfaringer, kompetencer, interesser og værdier.

Metoder: Et scoping review blev gennemført inden udviklingen af MA&R, for at kortlægge og vurdere den tilgængelige evidens for ergoterapi indenfor psykiatri. Principperne fra Lifestyle Redesign ® et aktivitetsorienteret gruppetilbud til ældre mennesker, der er vist effektivt i to lodtrækningsforøg, blev tilpasset nærværende målgruppe. Udgangspunktet for udviklingen af MA&R var teorier om transfer, og en kvalitativ syntese af deltager erfaringer fra Illness Management and Recovery (IMR), Individual Placement and Support (IPS) Lær at Tackle Angst og Depression, (LTAD) og Vendepunkter, de to sidste er gruppeforløb der ledes af mennesker med levede erfaringer med psykiske sygdomme, dvs. peers. Den kvalitative syntese, ledte til at peer-støtte (i gruppe og ved peer-medarbejder) og individuel støtte, sammen med fokus på meningsfulde aktiviteter og deres betydning for sundhed og recovery, blev kernekomponenter i MA&R. Indsatsen blev afprøvet i et multicenter, pragmatisk lodtrækningsforsøg. Forskningshypotesen var at MA&R sammen med den sædvanlige indsats var bedre i forhold til at øge engagement i meningsfulde aktiviteter (aktivitetsengagement), og forbedre livskvalitet, funktionsevne og personlig recovery. Deltagerne blev randomiseret 1:1, og tildelt 1) MA&R i tillæg til standardindsatsen, eller 2) standardindsatsen alene. Data blev indsamlet to gange, ved baseline før lodtrækning og ved MA&R`s afslutning. For at undersøge

hvordan deltagerne oplevelede deres engagement i aktiviteter, i forbindelse med MA&R, blev der gennemført et kvalitativt studie, bestående af semi-strukturerede individuelle interviews og tematisk analyse.

Resultater: I kortlægningen af den eksisterende evidens, publiceret mellem 2003 og 20018, blev der identificeret 21 originale studier og 3 systematiske reviews. Der var en betydelig variation, iblandt studierne i forhold til målgruppe, kontekst, interventionstype og studiedesign. Individualiserede interventioner og gruppeforløb viste lovende effekter i forhold til funktionsevne og aktivitetsengagement. Litteraturgennemgangen viste også at der var få studier af høj metodemæssige kvalitet der evaluererede effekten af ergoterapeutiske interventioner. Den kvalitative syntese viste at deltagerne igennem gruppediskussioner i IMR, Vendepunkter og LTAD, styrkede deres selvtillid og nærvær i sociale situationer, og at dette kunne overføres til bedre kvalitet i samværet med venner og familie, og et stærkere ståsted i kommunikation med fagprofessionelle. De oplevede også at de ved at spejle sig i erfaringerne fra peer-medarbejdere (i Vendepunkter og LTAD) udviklede strategier til egenomsorg, som kunne overføres til situationer i hverdagslivet. Gruppeformatet havde sine begrænsninger, i forhold til at kunne omsætte det lærte til hverdagsaktiviteter i det bredere perspektiv. Individuel støtte, som den blev erfaret af deltagerne i IPS kunne delvis imødekomme disse begrænsninger, hvis støtten var fleksibel, autentisk og rettidig. Resultaterne fra den kvalitative syntese blev anvendt i videreudviklingen af MA&R, med peer-støtte og individuel støtte som kerne komponenter. Mellem 2018 og 2020 blev 139 deltagere inkluderet i det kliniske forsøg og randomiseret enten til 1) MA&R + standardindsats(n=70) eller standardindsats alene (n=69) I alt blev 10 MA&R forløb gennemført, i psykiatriske ambulatorier, aktivitets-og samværstilbud og et rehabiliteringstilbud, ved Psykiatrisk Center København, Københavns Kommune, Svendborg Kommune og Odense Kommune. Deltagernes gennemsnitsalder var omkring 43, ca. halvdelen var mænd. De fleste var single, boede alene, havde ikke børn, og modtog førtidspension eller ressource ydelse. Ca. 82% af deltagerne gennemførte forløbet. I snit deltog de i 15 ud af 22 planlagte sessioner. Resultaterne viste at der ved follow up ingen signifikante forskelle var imellem interventionsgruppen og kontrolgruppen i forhold til aktivitetsengagement, funktionsevne, livskvalitet og personlig recovery. Post hoc analyser, viste at begge grupper oplevede en signifikant forbedring på flere af effektmålene, og at MA&R måske var bedre end standardindsatsen før COVID 19, men ikke under. Interviews med deltagere fra MA&R (n=13), sammenlignede MA&R med en praktisk tilgang til recovery, med muligheder for re-orientering, på meningsskabelse i det tilsyneladende banale og en understøttelse af et nyt syn på hverdagslivet, på egne præmisser.

Konklusion: MA&R var ikke bedre end standardindsatsen, når det gjaldt at øge aktivitetsengagement, eller forbedre funktionsevne, livskvalitet eller personlige recovery. På baggrund heraf kan vi ikke anbefale at MA&R implementeres i dens nuværende form. Deltagelsen i MA&R var relativt høj, og sammen med et relativt lille frafald tyder dette på at tilbuddet var acceptabelt og gav god mening for deltagerne De udeblivende effekter kan skyldes af kontrasten mellem MA&R og den sædvanlige indsats, var mindre end forventet, eller at forsøget delvis blev gennemført under COVID 19, hvilket begrænsede aktivitetsmulighederne, og muligvis har bidraget til at deltagerne ikke kunne få det fulde udbytte af indsatsen. Interviews med deltagerne peger på at MA&R først og fremmest kan understøtte et nyt perspektiv på hverdagsaktiviteter, og en oplevelse af kvalitet og tilfredshed med det man allerede gør, og at dette kan have en betydning for aktivitets engagement og recovery i et større perspektiv men ikke føre direkte til konkrete forandringer i hverdagen, i form af nye rutiner e.l.

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APPENDIX I

Papers

IJTR

SCOPING REVIEW

Occupational therapy interventions in mental health: a scoping review of recent evidence

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Abstract

Background/Aims Studies investigating the effect of occupational therapy in mental health are few. This scoping review aims to identify, present and assess studies that have investigated the effect of occupation- and activity-based/focused interventions performed by occupational therapists in mental health.

Methods The scoping review involved searching six databases, covering articles from 2003 to 2018. 'The Matrix Method' was used to describe and synthesise the content of the included studies. The Oxford Level of Evidence was used to rank the evidence, and The Critical Appraisal Skills Programme was used to assess the quality of the study.

Results A total of 21 original studies and 4 systematic reviews were included in this review. Interventions, approaches, programmes, training, and activities such as cooking, artwork, crafts, pottery, sports, calligraphy, horticulture, and music, organised individually or in groups, were investigated in the included studies. Individualised occupational therapy showed clinically significant improvements in social functioning and cognition, promising results were found on supported employment and education.

Conclusions Few high-quality studies that have investigated the effect of occupation-and activity-based/focused interventions performed by occupational therapists in mental health were found. This scoping review highlights the importance of future high quality studies to support evidence-based practice within mental health occupational therapy.

Key words: ■ Evidence-based practice ■ Interventions ■ Mental health ■ Occupational therapy ■ Review

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INTRODUCTION

Occupational therapy has been offered in mental health for decades (Creek and Lawson-Porter, 2007). Occupational therapists assert to support patients' journeys of recovery through engagement in meaningful occupation (Casey, 2011; Doroud et al, 2015). Psychiatric disability occurs when mental illness significantly limits the involvement in major life activities and roles, such as working, living and interacting

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with friends and family (Corrigan et al, 2012). Traditionally, severe mental illness, such as bipolar disorders and schizophrenia spectrum disorders are associated with a significant risk of disability (Ruggeri et al, 2000). However, individuals with common mental ilnesses, such as depression and anxiety disorders, also risk disability and limitations in participation in daily life (Cabello et al, 2012; Saris et al, 2017). Living with severe or common mental illnesses may cause periodic episodes that require mental health treatment and support. Having access to good quality and effective rehabilitation services is essential to people with psychiatric illnesses (Slade, 2009; Le Boutillier et al, 2011; World Health Organization and The World Bank, 2011). Occupational therapists provide rehabilitation services to people whose mental illness interferes with satisfactory participation in everyday occupations (Kielhofner, 2008; Brown et al, 2011).

The primary therapeutic agent in occupational therapy is meaningful activities (Kielhofner, 2008). The concept of occupation- or activity-based and occupation-focused interventions are widely used by occupational therapists to define occupation as the core of the profession where occupational performance is assessed, and performing activities and tasks acts as both the aim and the primary therapeutic means (Fisher, 2013). Occupational therapists in mental health use conceptual models, theoretical frameworks, assessment and screening tools to inform clinical decisions. The use of models, theory and tools is not sufficient when wanting to implement effective interventions based on recent evidence; best available evidence is also needed. Evidence-based practice assesses and uses available evidence to support clinical practice and improve the profession by making interventions and treatments more robust (Blair et al, 2008; Kielhofner, 2008; Johnston and Case-Smith, 2009).

A review of studies investigating the effect of occupational therapy interventions targeting adults over the age of 18 years with psychiatric ilnesses could give occupational therapists in mental health an overview of recent evidence, which could guide the implementation of effective interventions. In this review, occupational therapy interventions are defined as occupation-based and occupation-focused interventions, defined by Fisher as interventions that are not only focused on occupation but also based on occupation-based methods (Fisher, 2013), which are delivered by occupational therapists in a mental health setting. This scoping review aims to identify, present and assess studies that have investigated the effect of occupation- and activity-based/focused interventions performed by occupational therapists in mental health.

METHODS

The review was designed as a scoping review and guided by Arksey and O'Mally's (2005) five steps in performing a scoping review:

- Identify and formulate a research question
- Search and choose relevant studies
- Give an overview of studies
- Extract relevant data
- Give a summary of the results.

The research question posed was: what is the recent evidence to support occupational therapy interventions in mental health settings? A total of six databases were searched and relevant studies were chosen according to the outlined criteria. An overview of the included studies with relevant data was given in *Appendices 1* and *2* along with a summary of the findings presented. Furthermore, a critical quality assessment was added in order to be able to assess the quality of the study findings as presented in the aim of the study.

Databases searched

The following six electronic databases covering mental health were searched: PubMed, Embase, Cinahl, PsychInfo, OT Seeker and Cochrane Library.

Search strategy

The search strategy was inspired by the PICO model (da Costa Santos et al, 2007).

Population (P) was defined as people aged 18 years and over with mental illness. A broad definition of mental illness was chosen to locate relevant studies, including both common and severe mental ilnesses.

Interventions (I) were, according to Fisher (2013), defined as occupation- or activity-based and focused interventions, delivered by occupational therapists in mental health.

Comparisons (C) of effect, effectiveness, and evidence were chosen as search terms as outlined in *Table 1*, searching for randomised controlled trials, quasi-experimental trials and follow up studies.

Outcome (O) was not specified in the search.

Table 1. Search strategy terms

Search strategy 1
'Occupational therapy' AND 'mental health' OR 'mental illness' AND randomised*
Search strategy 2
'Occupational therapy' OR 'Occupation focused intervention' OR 'occupation based intervention' AND 'mental health' OR 'mental illness' AND randomised*
Search strategy 3
'Occupational therapy' OR 'activity focused intervention' OR 'activity based intervention' AND 'mental health' AND 'follow up'*
Search strategy 4
'Occupational therapy' AND 'schizophrenia' OR 'community mental health' AND randomised*
Search strategy 5
'Occupational therapy' AND 'mental health' AND 'evidence'

Inclusion criteria

Original full-text articles and reviews in the English language investigating the effect of occupational therapy interventions published in international peer-reviewed journals from January 2003 to January 2018. The initial search was carried out in 2013 and in the second search the search was expanded to another 5 years. Randomised controlled trials, quasi-randomised studies, quasi-experimental trials and follow-up studies were included.

Exclusion criteria

Overviews, editorials, comments, theoretical papers, and non-peer-reviewed papers, dissertation, thesis, participants with learning disabilities and forensic mental health were excluded; because of the complexity of the population and legislation issues involved, it was not the target group for this type of review.

Criteria for ranking the evidence of original studies

The Levels of Evidence as outlined by The Oxford Centre for Evidence-Based Medicine Levels of Evidence Working Group (2011) were used to rank the included studies in levels of evidence. The Oxford Centre for Evidence-Based Medicine

Levels of Evidence is an evidence ranking scheme, used to appraise the quality of evidence for therapeutic effects. A total of 11 studies were ranked as level 2, as they were conducted as randomised controlled trials. Of these, 7 of the studies were, however, pilot randomised controlled trials and had a small sample size. The remaining 4 studies were designed as large-scale randomised controlled trials. A total of 10 studies were ranked as level 3, as they did not have a randomised design or a control group.

Evaluation of the quality of the included studies

To appraise the methodological quality of the included reviews and original studies, The Critical Appraisal Skills Programme (2018) was used. The Critical Appraisal Skills Programme is a set of tools designed to assess the quality of the research findings.

Review process

The first and second authors carried out the search, selected and quality rated and hand-searched all articles. Articles were screened and selected independently and compared according to the outlined research question and inclusion criteria. The last author was consulted if doubt appeared. Following full-text reading, articles were abstracted chronologically in a matrix (Garrard, 2010). Reviews were abstracted in six column topics:

- Author, year and country (column 1)
- Aim (column 2)
- Method (column 3)
- Results (column 4)
- Intervention (column 5)
- Assessment (column 6).

Original studies were abstracted in eight column topics:

- Author, year and country (column 1)
- Aim (column 2)
- Design (column 3)
- Participants (column 4).

Four additional columns topics that related to the aim of the review were added (Garrard, 2010):

- Intervention (column 5)
- Outcome (column 6)
- Outcome measures (column 7)
- Quality rating (column 8).

RESULTS

This scoping review aimed to identify, present and assess studies that have investigated the effect of occupation-and activity-based/focused interventions performed by occupational therapists in mental health. The outlined research question: What is the recent evidence to support occupational therapy interventions in mental health settings? guided the search and selection of studies. The initial search, carried out in 2013, produced 3472 hits (*Figure 1*). A total of 3419 articles were excluded after reading the title and abstract, 53 articles were selected for further reading; 17 out of the 53 articles were excluded as they did not have a study design as outlined in the inclusion criteria.

Out of the 53 articles, 36 (16 reviews and 20 original studies) were selected for in-depth reading and quality rating. After full-text reading and critical assessment

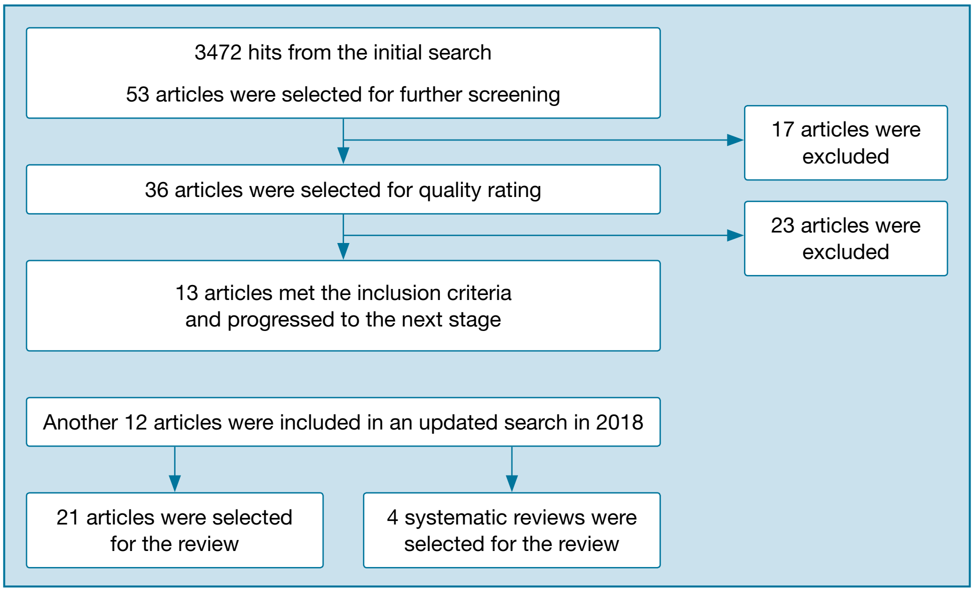

Figure 1. Flowchart of selection process

of study design and methods, 23 articles were excluded as they did not investigate the effect of interventions. A total of 13 articles were included, among them were 10 original studies and 3 systematic reviews after the initial search in 2013. An updated search in January 2018 identified another systematic review and 11 studies.

In total, 4 systematic reviews and 21 original studies met the inclusion criteria and were included in this scoping review.

Systematic reviews

A total of four systematic reviews were included. Arbesman and Logsdon (2011) investigated studies evaluating the effectiveness of occupational therapy interventions focusing on participation and performance in occupations related to paid and unpaid employment and education for people with severe mental illness. The systematic review included occupation- and activity-based interventions addressing performance skills, aspects of the environment, activity demands, and personal factors. A total of 46 papers: 37 high-level pieces of evidence, 5 second level, and 4 third level studies were included in the systematic review. Arbesman and Logsdon (2011) concluded that evidence is strong for the efficacy of supported employment, specifically the Individual Placement and Support model compared to conventional vocational rehabilitation. The interventions are generic and fit within the scope of occupational therapy (Arbesman and Logsdon, 2011).

Bullock and Bannigan (2011) investigated the effectiveness of activity-based groups. Three papers from 1985, 1986 and 1999 were included. The interventions investigated in the studies were activity-based group work compared to oral group work and had a small sample size (19–25 participants). The outcome of interventions was measured according to symptoms and functional level. Studies lacked a description of randomisation, baseline characteristics, and potential confounders. Intervention groups showed a positive effect on social interaction, behaviour, and reduction of symptoms. Bullock and Bannigan (2011) concluded that activity-based group interventions were not investigated sufficiently; further randomised controlled studies are needed to test the effectiveness of interventions (Bullock and Bannigan, 2011).

Gibson et al (2011) investigated studies evaluating the effectiveness of occupational therapy in mental health interventions by focusing on recovery in areas of community integration and life roles. The search terms used were interventions within the scope of occupational therapy practice: instrumental activities of daily living and education and work. The interventions investigated were occupational- and activity-based interventions, and generic mental health services such as Individual Placement and Support, and social skills training; 52 papers published in or after 1990, with evidence levels of 1–3, were included. Gibson et al (2011) concluded that evidence on the effectiveness of social skill training and supported employment is moderate to strong. Evidence of instrumental activities of daily living, supported education, and neurocognitive training is moderate (Gibson et al, 2011).

Ikiugu et al (2017) investigated the effectiveness of theory-based occupational therapy interventions in improving occupational performance and wellbeing. The search terms used were: occupational therapy, occupational therapy interventions, mental health, theoretical conceptual practice models, occupational performance, and wellbeing. The meta-analysis included 11 randomised controlled trials with a total of 520 adult participants with a mental health diagnosis.

Outcomes were either occupational performance or wellbeing, or both. The results of the meta-analysis of 11 included studies indicated a medium effect of the intervention on improving occupational performance (mean Hedge's g 5 0.50, Z 5 4.05, $P<0.001$) and a small effect on wellbeing (mean Hedge's g 5 0.46, Z 5 4.96, $P<0.001$). Ikiugu et al, 2017 concluded that theory-based occupational therapy interventions may be effective in improving occupational performance and wellbeing among people with a mental health diagnosis and should be an integral part of rehabilitation services in mental health (Ikiugu et al, 2017).

Original studies

A total of 21 studies published in international journals from January 2003 to January 2018 were included. The studies were carried out in:

- Brazil (Buchain et al, 2003; Vizzotto et al, 2016)
- The UK (Cook et al, 2009; Lambert et al, 2010)
- Canada (Edgelow and Krupa, 2011; Wisenthal et al, 2018)
- The USA (Gutman et al, 2009; Chapleau et al, 2012; Schindler and Sauerwald, 2013),
- The Netherlands (Hees et al, 2013)
- Israel (Katz and Keren, 2011; Lipskaya-Velikovsky et al, 2016), China (Poon et al, 2010)
- Iran (Foruzandeh and Parvin, 2013)
- Japan (Tatsumi et al, 2011; Yamashita et al, 2012; Hoshii et al, 2013; Shimada et al, 2016)
- Taiwan (Chen et al, 2015)
- Sweden (Eklund et al, 2014, 2017).

Study design

Of the 21 studies:

- Four studies were designed as large-scale randomised controlled trials (Lambert et al, 2010; Hees et al, 2013; Eklund et al, 2014; 2017)
- Three were pilot randomised controlled trials (Cook et al, 2009; Edgelow and Krupa, 2011; Vizzotto et al, 2016)
- Three were small-scale randomised controlled trials (Buchain et al, 2003; Tatsumi et al, 2011; Chen et al, 2015)
- Three were quasi-experimental design (Gutman et al, 2009; Katz and Keren, 2011; Shimada et al, 2016)
- Five were follow-up studies (Poon et al, 2010; Chapleau et al, 2012; Yamashita et al, 2012; Lipskaya-Velikovsky et al, 2016; Wisenthal et al, 2018)

- One was a comparative study (Hoshii et al, 2013)
- Two studies were surveys (Foruzandeh and Parvin, 2013; Schindler and Sauerwald, 2013)
- One randomised controlled trial study involved an economic evaluation (Lambert et al, 2010).

Participants

Participants varied from 10 to 215 patients, diagnosed with:

- Serious mental illness (Edgelow and Krupa, 2011; Gutman, 2011; Chapleau et al, 2012; Eklund et al, 2014; 2017)
- Schizophrenia (Buchain et al, 2003; Cook et al, 2009; Poon et al, 2010; Katz and Keren, 2011; Tatsumi et al, 2011; Foruzandeh and Parvin, 2013; Hoshii et al, 2013; Lipskaya-Velikovsky et al, 2016; Shimada et al, 2016; Vizzotto et al, 2016)
- Major depression (Hees et al, 2013; Chen et al, 2015; Wisenthal et al, 2018)
- Panic disorder (Lambert et al, 2010)
- Psychiatric symptoms without diagnostic specification (Yamashita et al, 2012; Schindler and Sauerwald, 2013).

Interventions

A variety of occupation- and activity-based/focused interventions were investigated in the included original studies (*Appendix 2*), defined as interventions, approaches, models, programmes, training, and activities.

Interventions

Interventions were described as:

- Return to work (Hees et al, 2013; Wisenthal et al, 2016)
- Individualised (Cook et al, 2009; Shimada et al, 2016)
- Goal-oriented (Vizzotto et al, 2016)
- Activity-based and tailor-made (Eklund et al, 2014).

Approaches

Approaches were described as:

- Client-centered (Cook et al, 2009)
- Goal-oriented and strategy learning (Katz and Keren, 2011; Vizzotto et al, 2016)
- Activity-based (Buchain et al, 2003)
- Lifestyle-oriented (Lambert et al, 2010; Eklund et al, 2017).

Models

Models were described as consulted and goal-oriented (Chapleau et al, 2012).

Programmes

Programmes were described as:

- Supported education (Gutman et al, 2009; Schindler and Sauerwald, 2013)
- Supported employment (Schindler and Sauerwald, 2013)
- Self-management (Chen et al, 2015)
- Time-use (Edgelow and Krupa, 2011).

Training

Training was described as symptom management and work habits (Poon et al, 2010).

Activities

Activities were described as:

- Subject-chosen (Hoshii et al, 2013)

- Cooking (Poon et al, 2010)
- Art therapy, crafts, pottery, sports, calligraphy, horticulture and music (Yamashita et al, 2012; Foruzandeh and Parvin, 2013), and organised individually or in groups.

Outcome measures

Outcome measures (*Appendix 2*) used in the included original assessed:

- Psychiatric symptoms (Lambert et al, 2010; Tatsumi et al, 2011; Yamashita et al, 2012; Foruzandeh and Parvin, 2013; Chen et al, 2015)
- Psychosocial functioning (Cook et al, 2009; Hoshii et al, 2013; Vizzotto et al, 2016; Eklund et al, 2017)
- Cognitive functioning (Katz and Keren, 2011; Chapleau et al, 2012; Lipskaya-Velikovsky et al, 2016; Shimada et al, 2016)
- Occupational performance (Chapleau et al, 2012; Schindler and Sauerwald, 2013)
- Work and student ability (Gutman et al, 2009; Poon et al, 2010; Hees et al, 2013; Wisenthal et al, 2018)
- Activity engagement (Edgelow and Krupa, 2011; Eklund et al, 2017)
- Satisfaction with daily occupations (Eklund et al, 2014; 2017)
- Quality of life (Lambert et al, 2010; Chen et al, 2015).

Effect of interventions

Individualised occupational therapy showed clinically significant improvements in social functioning (Cook et al, 2009) and cognition (Shimada et al, 2016). An individual time use intervention showed an increase in activity engagement (Edgelow and Krupa, 2011) and in a group-based lifestyle intervention (Eklund et al, 2017).

Supported education programmes helped the participants increase their skill level in academic areas, and social skills, as well as improvement in personal goals (Gutman et al, 2009; Schindler and Sauerwald, 2013), activity-based interventions showed an effect on psychopathological outcomes such as positive and negative symptoms in schizophrenia (Foruzandeh and Parvin, 2013; Hoshii et al, 2013; Vizzotto et al, 2016).

Lifestyle interventions to patients living with panic disorders and depression had an impact on symptoms and suicidal ideation (Lambert et al, 2010; Chen et al, 2015). Vocational rehabilitation services had a positive impact on productive roles 3 months after discharge in patients living with schizophrenia disorders (Poon et al, 2010) and on work relating coping and self-efficacy in a group of sick-listed employees with major depression (Hees et al, 2013; Wisenthal et al, 2018).

DISCUSSION

The aim of this scoping review was to identify, present and assess studies that have investigated the effect of occupation- and activity-based/focused interventions performed by occupational therapists in mental health. The recent evidence to support occupational therapy interventions in mental health settings is limited. However, there are some promising results of interventions; the effect of individual occupational therapy showed clinical improvements on social functioning and cognition. Individual time-use interventions and group-based lifestyle interventions showed an increase in activity engagement and supported education programmes helped increase academic and social skills. Lifestyle interventions seem to have a positive impact on symptoms and suicidal ideation on patients with panic disorder and depression and vocational rehabilitation show positive results on productive roles, work-related coping and self-efficacy.

A scoping review of qualitative studies performed by Doroud et al (2015) demonstrated that being engaged in meaningful activities is experienced as a break from hassles caused from troubling symptoms and worries, as well as a mean to rediscover forgotten or new resources, and to reconnect with daily life and rhythm (Doroud et al, 2015). The findings from this scoping review support the findings summarised by Doroud et al (2015) and indicate that individual-tailored occupation and activity-based/focused interventions that enable participation in meaningful activities can be a valuable contribution to mental health rehabilitation.

Four systematic reviews and 21 original studies investigating the effect of interventions were included, conducted in various international settings. Compared to the systematic reviews by Arbesman and Logsdon (2011), Bullock and Bannigan (2011), Gibson et al (2011) and Ikiugu et al (2017), this scoping review applied a much broader search strategy in order to provide a comprehensive overview of the evidence and the possible research gaps. Overall, the findings demonstrate an increase in studies investigating the effect of occupation- and activity-based/focused interventions over the past 10 years. However, the ranking and quality assessment showed that there were methodological weaknesses in several of the included studies, which call for critical reflections before implementing the interventions in clinical practice.

The scoping review shows that for the past 5 years, research has expanded, from 10 original papers in 2013 to 21 in 2018. This is promising, although there is a need for more high-quality studies. Evidence of high quality is necessary to determine which interventions occupational therapists should employ in practice. Worldwide, occupational therapists use conceptual models such as The Model of Human Occupation (Kielhofner, 2008) and The Canadian Model of Occupational Performance and Engagement (Polatajko et al, 2007), and reasoning models such as The Occupational Therapy Intervention Process Model (Fisher and Jones, 2009). The Canadian Practice Process Framework (Craik et al, 2007) or the Canadian Model of Client-Centred Enablement (Phillips, 2007).

Models, theory and tools are needed in occupational therapy practice, but as this review shows, limited studies have investigated the effect of the occupation and activity based/focused interventions. Intervention studies with a high level of evidence are needed in order to support evidence-based practice in occupational therapy. It is our responsibility not only to select and implement models and assessment tools appropriate to practice, but also to be aware of evidence to complement our practice (Kielhofner, 2009). Interventions included in this scoping review shows promising results on the use of individually tailored and activity-based/focused interventions, which calls for further development and research.

Limitations

A limitation of our review could be the chosen time period for the search; however former reviews did not seem to find more convincing evidence of relevance before 2003. A potential source of bias could also be the exclusion of papers in a non-English language. In addition, only quantitative studies were included as they are suitable designs when testing the effect of interventions. On the other hand, qualitative studies could help identify interventions of importance from the patients' perspective, which could guide future randomised controlled studies.

CONCLUSIONS

The recent evidence to support occupational therapy in mental health is limited, but for the past 5 years, several studies have investigated the effect of interventions. Few high-quality studies have investigated the effect of the occupation- and activity-based and focused interventions commonly performed by occupational therapists in mental health. Individually tailored and group-based interventions seem to have promising results and so does supported education programmes and vocational rehabilitation. There is a need to further develop individually tailored interventions used by occupational therapists in mental health. Further studies of high quality are needed to help fulfil the gap in research evidence, especially large-scale randomised controlled trials and intervention studies of high quality is needed if evidence-based practice in occupational therapy in mental health is to be further developed.

The knowledge base within occupational therapy in mental health needs to be further expanded to fulfil future challenges in supporting patients' individual recovery process. Validated occupational therapy assessment tools and conceptual models are an important contribution to improve practice in mental health. However, the evidence base underpinning the commonly used interventions needs to be further developed to support and guide occupational therapists clinical decision-making in mental health.

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Conflict of interest

The authors declare that there are no conflicts of interest.

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Appendix 1. Systematic reviews

Author, year and country	Aim	Method	Results	Intervention	Evaluation
Arbesman and Logsdon (2011) USA	To investigate research literature evaluating the effectiveness of interventions within occupational therapy's scope of practice that focus on participation and performance in occupations related to paid and unpaid employment and education for people with serious mental illness	Papers published in peer-reviewed journals, English-language articles after 1990. Severe mental illness, age 18–65 years. Interventions within the scope of occupational therapy practice Evidence Level I (ie randomised controlled trials, systematic reviews, and meta-analyses), Level II (ie, non-randomised controlled trials such as cohort studies), and Level III (ie, pre-test/post-test, one-group designs)	46 articles included Work Programmes*:* Supported employment and vocational rehabilitation evidence is strong especially Individual Placement and Support Education Programmes*:* supported education programmes at the post-secondary level are effective, in addition supported employment plus cognitive or social skills training showed good effect Homemaking, parenting, and environmental supports programmes: comparing cooking skills training in the home to cooking skills training in the clinic showed significant improvement in skills for both groups	Occupation- and activity-based interventions Interventions addressing performance skills, aspects of the environment, activity demands, and client factors Work, education and homemaking, parenting and environmental support programmes	Studies included, at evidence level 1–3 Interventions focus on work, education and home skills
Bullock and Bannigan (2011) England	To find out if activity-based group work is effective in helping people with severe and enduring mental illness in community settings improve their functional ability, reduce their mental health symptoms, or both	A wide-ranging search strategy, including electronic searching, hand searching, citation searching, and use of grey literature. Heterogeneity and flaws in quality meant it was not possible to make specific inferences for practice from the studies. No reviews were found. No time limit for the search	Three articles included All studies showed that activity-based group work was more effective than verbally based group work, studies with social interaction outcomes were statistically significant for activity-based groups compared with verbally based groups No evidence exists to either support or refute the effectiveness of activity-based group work in either improving functional ability or reducing mental health symptoms of community-living adults with severe mental illness	Activity-based group work aimed to develop skills and/or encourage participation in social interaction, all carried out by occupational therapists	Three studies included, level 2–3 of evidence Older studies were included Limited to activity-based group work interventions

Gibson et al (2011) USA	To investigate research literature evaluating the effectiveness of occupational therapy interventions focusing on recovery in the areas of community integration and normative life roles for people with serious mental illness	Studies published since 1990 in English language, peer-reviewed journals. Participants aged between 18 and 65 with a diagnosis of severe mental illness. Interventions within the scope of occupational therapy practice; Studies at evidence level 1–3. Search terms for interventions: instrumental activities of daily living, education and work	52 articles included Evidence exists to support efficacy of occupational therapy interventions focused on components of recovery from serious mental illness Moderate to strong evidence for social skill training and supported employment Moderate evidence for effectiveness of interventions in other areas, including instrumental activities of daily living, training, supported education and neurocognitive training	Interventions within the scope of occupational therapy: Social participation Instrumental activities of daily living Work and education Neuro-cognitive training Client-centred Context and environment	Studies included, at evidence level 2–3 A variety of interventions were tested
Ikiugu et al (2017) USA	To estimate the effectiveness of theory-based occupational therapy interventions in improving occupational performance and wellbeing among people with a mental health diagnosis	Criteria for inclusion: participants aged 18 years or older); participants with mental health diagnosis; randomised controlled trial design; wellbeing, occupational performance, or both as dependent variables. Parametric statistics were used to analyse data; search period between 1995 and June 2016	11 papers included. Results indicated a medium effect of intervention on improving occupational performance (mean Hedge's g 5 0.50, Z 5 4.05, *P*<0.001) and a small effect on wellbeing (mean Hedge's g 5 0.46, Z 5 4.96, *P*<0.001)	Theory-based occupational therapy interventions guided by The Behavioural/ Cognitive–Behavioural theoretical conceptual practice model, The Canadian model of Occupational Performance and Engagement the Cognitive Disabilities model, unspecified client-centered models, or a psychodynamic model	

Appendix 2. Original studies

Author, year and country	Aim	Design	Participants	Intervention	Outcome	Outcome measures	Evaluation
Buchain et al (2003) Brazil	To investigate if occupational therapy is effective when added to a psycho-pharmacological treatment	Randomised controlled trial study	26 patients with treatment resistant schizophrenia	The experimental group received psycho-pharmacological treatment with clozapine plus sessions of occupational therapy. The control group received only clozapine. Free choice of activities was used both individually and group activities	Occupational therapy intervention was effective mainly from month 4 to the end of the intervention. Combination of occupational therapy and clozapine showed to be more effective than the use of clozapine alone Occupational therapy represented an additional therapeutic option for patients with treatment resistant schizophrenia	The Scale for Interactive Observation in Occupational Therapy	Randomised controlled trial South American setting No confidence interval No *P*-value Blinding not mentioned Level 2
Cook et al (2009) UK	To investigate the effectiveness of occupational therapy for people with psychotic conditions	Pilot randomised controlled trial	42 participants with schizophrenia or other psychotic conditions	Individualised occupational therapy up to 12 months in two community mental health settings, compared to treatment as usual	Occupational therapy group showed clinically significant improvements, individualised occupational therapy may contribute to recovery	Social functioning scale (assessment of negative symptoms)	Pilot randomised controlled trial and qualitative methods Community setting Small sample size No power calculation Low confidence interval Level 2
Gutman et al (2009) USA	To assess the effectiveness of a supported education programme for adults with psychiatric disabilities	Quasi-experimental design	38 participants with psychiatric disabilities	An experimental group (n=21) who received supported education services or a control group (n=17) who received treatment as usual. The Bridge Programme ran twice a week for 6 weeks in the occupational therapy programme	Helped participants to increase their skill level in basic academic areas, improve professional behaviour and social skills needed for school and work settings, and gain the confidence to test their skills	The Student Role Scale, The Task Skills, Interpersonal Skills, and School Behaviour Scales, Participant Overall Satisfaction Scale	Quasi-experimental design Randomised to experimental or control group Small sample size 1 year follow-up planned No information control group Level 2

Appendix 2. Original studies (Continued)

Lambert et al (2010) UK	To assess the cost-effectiveness of an occupational therapy-led lifestyle approach to treating panic disorder in primary care compared with routine general practitioners' care	Randomised controlled trial study and economic evaluation	170 adults with panic disorder	The occupational therapy-led lifestyle intervention was provided by trained research occupational therapists. The intervention addressed diet pattern, fluid intake, exercise and habitual lifestyle drug use (caffeine, alcohol and nicotine)	If the maximum willingness to pay per additional quality adjusted life years is £30 000, then there is an 86% chance that a lifestyle intervention may be considered to be value for money over 10 months	Beck anxiety inventory Quality adjusted life years The EQ-5D (European Quality of Life) questionnaire	Randomised controlled trial Unblinded trial Several participants Economical evaluation included Level 2
Poon et al (2010) China	Examine the vocational outcomes of young people with early psychosis after their participation in an occupational therapy programme and explore factors linked to patient achieving successful outcomes	Survey with follow-up	147 Patients between 15 and 25 years of age, early psychosis or schizophrenia 3 months after discharge	Symptom management, work habit training, enrichment of the work experience, building social support and cultivation of insight into illness were important strategies related to the successful adoption of a productive role	Retrospective review of case management plans and outcomes, 53.7% of the patients were still engaged in productive roles (vocational training, work or study) 3 months after discharge from the occupational therapyprogramme	Counting who is in productive roles and who is not	Survey with follow-up Retrospective and exploratory study design No control group Large sample size (*n*=147) Level 3
Tatsumi et al (2011) Japan	Determine whether occupational therapy can improve the interpersonal relationships and negative symptoms of hospitalised patients	Small scale randomised controlled trial study	38 hospitalised chronic schizophrenia patients with severe negative symptoms for more than 10 years	Occupational therapy group participated in cooking activities once a week for 15 weeks, while the control group did not The cooking activities had the following three elements: participation in activities; having a goal; and doing the activities step by step	Comparison of the two groups showed no significant differences in total Brief Psychiatric Rating Scale, for the Assessment of Negative Symptoms, Rehabilitation Evaluation Hall and Baker scale, or Profile of Mood States scale score or seating location Intra-group data comparison before and after the intervention showed significant changes in the occupational therapy group	Scale for the Assessment of Negative Symptoms, the Brief Psychiatric Rating Scale, the Rehabilitation Evaluation Hall and Baker scale The Profile of Mood States scale Seating preferences	Randomised controlled trial small scale study Small sample size (*n*=38) Insufficient description of intervention, observation-based data collection, cultural bias Level 2

Appendix 2. Original studies (Continued)

Katz and Keren (2011) Israel	To compare the effectiveness of occupational goal intervention in clients with schizophrenia to the Frontal Executive Programme and a control group	Quasi-experimental design	18 patients with schizophrenia or schizo-affective disorder Age 20–38 years	Occupational goal intervention and strategy learning using activities and everyday tasks for 6–8 weeks: (1) food preparation (2) money management (3) reading, writing, and using computers for information. Frontal Executive Programme involves training for neurocognitive rehabilitation based on a process-specific approach Consists of three modules (cognitive shift, working memory, and planning)	No significant differences among the three groups (two study groups and one control) on pre-test–post-test change Significant differences within groups before and after intervention and moderate to high effect sizes The occupational goal intervention group showed relative improvement on all measures, activity and participation	Wisconsin Card Sorting Test. Wechsler Adult Intelligence Scale—Digit Span Forward and Backward Behavioural Assessment of the Dysexecutive Syndrome Executive Functions Performance Test and Instruments: Activity and participation Outcome Measures	Quasi-experimental with 6 months follow-up Small sample size (n=18) High drop-out rate (50 %) Blinding not mentioned Level 3
Edgelow and Krupa (2011) Canada	To assess the efficacy and clinical utility of a new occupational time-use intervention Action Over Inertia, designed to improve occupational balance and engagement	Pilot randomised controlled trial	18 community-dwelling people with serious mental illness	Action Over Inertia intervention: Determining the need for change and securing investment Reflecting on current occupational balance and engagement patterns Providing information about the relationship between serious mental illness and occupational balance and engagement Long-term goal planning and support Ongoing monitoring and refinement of plans	Treatment group participants increased their occupational balance by spending an average of 47 minutes more per day in activity than the control group	Profiles of Occupational Engagement for People With Schizophrenia were collected from 24-hour diaries	Pilot randomised controlled trial Small sample size Blinding not mentioned Level 2
Yamashita et al (2012) Japan	To investigate the effects of single and repeated administrations of psychiatric occupational therapy on psychiatric symptoms and determine whether effects can be predicted	Follow-up study	215 participants with psychiatric symptoms (152 inpatients and 63 outpatients)	Art therapy, crafts, pottery, sports, calligraphy, horticulture, cooking and music planned in 25 sessions	Short-term effect shown, whereas repeated psychiatric occupational therapy cannot induce long-term effect on psychiatric symptoms	Psychiatric symptoms measured: Depressive mood, tension, irritability Anxiety and fatigue subjectively measured just before and just after each psychiatric occupational therapy by using a Visual Analogue Scale	Follow-up study design Insufficient description of intervention Non-validated outcome measures Large drop-out rate No control group Level 3

Appendix 2. Original studies (Continued)

Chapleau et al (2012)	To provide occupational therapy consultation in order to: 1. Stabilise or improve housing status 2. Achieve client goal attainment	Repeated-measure experimental design	57 people with severe mental illness who were homeless or at risk of homelessness	The use of an occupational therapy consultation model in a case management programme for people who are homeless	Significant improvement in housing stability and goal attainment	Allen Cognitive Level Screening Device and Canadian Occupational Performance Measure and housing scales	Follow-up study design Not randomised Small sample Level 3
Schindler and Sauerwald (2013) USA	To examine outcomes of the first 4 years (2005–2009) of the Bridge Programme, an occupational therapy programme that incorporates principles of supported education and supported employment	Quantitative one-group pre-test–post-test survey design and post-test qualitative focus groups	48 patients with various psychiatric symptoms	Client-centred, occupation-based supported education and employment programme	Increased client scores on satisfaction and performance of occupational performance problems. Participants reported that they improved in 95–100% of goals they established	Canadian Occupational Performance Measure	Survey study design Small sample size No comparison group Level 3
Foruzandeh and Parvin (2013) Iran	To investigate the effects of occupational therapy on symptoms of patients with schizophrenia	Survey study	Patients diagnosed with schizophrenia	The samples consisted of patients with schizophrenia who were divided randomly into intervention and usual treatment groups (30 patients in each group). Intervention: art therapy, crafts, pottery, sports, calligraphy, horticulture and music	Participation in activities seems to have a short-term effect on psychiatric symptoms	A scale for the assessment of positive and negative symptoms	Survey study design Small sample size Level 2
Hoshii et al (2013) Japan	To compare the therapeutic effects of subject-chosen and therapist-chosen activities in occupational therapy for inpatients with chronic schizophrenia	Prospective comparative study	59 patients diagnosed with chronic schizophrenia	6 months' occupational therapy, participating in either activities of their choice (subject-chosen activity group, n=30) or activities chosen by occupational therapists based on treatment recommendations and patient consent (therapist-chosen activity group, n=29)	Suspiciousness and hostility scores of the positive scale and preoccupation scores of the general psychopathology scale significantly improved in the subject-chosen activity group compared with the therapist-chosen activity group. No significant differences in psychosocial functions between the two groups	The Positive and Negative Syndrome Scale and the Global Assessment of Functioning Scale were used to evaluate psychiatric symptoms and psychosocial function	Comparative study design Small sample size Level 3

Appendix 2. Original studies (Continued)

Hees et al (2013) Netherlands	Evaluate whether adjuvant occupational therapy can improve the effectiveness of treatment as usual	Randomised controlled trial study	117 participants sick listed employes with major depression	Fast return to work and improving work-related coping and self-efficacy occupational therapy intervention consisted of 18 sessions (9 individual sessions, 8 group sessions and a meeting with the employer) Intervention conducted by two experienced occupational therapists who had received extensive training in the intervention protocol	The groups did not significantly differ in their overall work participation Treatment as usual and occupational therapy did show greater improvement in depression symptoms, an increased probability of long-term symptom remission, and increased probability of long-term return to work in good health. Intermediate outcomes were work-related, coping and self-efficacy	Work participation (hours of absence and duration until partial/full return to work) and depression, at-work functioning, and health-related functioning	Randomised controlled trial Focus on depression and return to work Large sample size Intervention protocol Level 2
Eklund et al (2014) Sweden	To investigate the effectiveness of a tailor-made intervention to improve day centre services specifically tailored for each day centre to bridge gaps identified in their services	Randomised controlled trial based on cluster randomisation	108 participants, 57 from the intervention centres and 51 from the comparison centres	The development of the intervention occurred in three ste ps: 1: Users and staff in all units filled out a questionnaire, the Estimation of Perceived Meaningfulness in Day Centres 2: An education and workshop package for the staff 3: The staff set goals for how to improve services	There was no difference between the intervention group and the comparison group, regarding change in perceived meaningfulness between the measurements points, for either the attendees	Satisfaction with Daily Occupations A specific questionnaire was devised to characterise the centre's ability to generate meaningful occupations for the attendees	57 in the intervention group Tailor made intervention Level 2
Chen et al (2015) Taiwan	To examine the incremental efficacy of a 24-session Life Adaption Skill Training programme on the quality of life, symptom reduction, and occupational and environmental improvement for persons with depression	Single-blinded randomised controlled trial	68 adults with depressive disorders	Life Adaption Skill Training a manualised intervention programme based on belief of enhanching wellbeing through occupational participation with different strategies and skills. 24 group sessions, 1.5 hour twice a week for 12 weeks	Significant incremental improvements with moderate to large between-group effect sizes on their level of anxiety and level of suicidal ideation when compared to control group	The primary outcome measure World Health Organization Quality of Life-BREF-Taiwan version. Secondary outcome measures Occupational self-assessment, the Mastery scale, the Social support questionnaire, the Beck anxiety inventory, the Beck depression inventory-II, and the Beck scale for suicide ideation	Small sample size Large drop-out rate Level 2

Appendix 2. Original studies (Continued)

Shimada et al (2016) Japan	Examined the effect of an individualised occupational therapy programme	Quasi-experimental controlled trial	51 patients with schizophrenia or schizoaffective disorder between 20 and 65 years	A combination of effective psychosocial treatment programmes: Motivational interviewing Self-monitoring IndividualiSed visits Handicraft activities IndividualiSed psycho-education Discharge planning Activity-oriented group treatment	Participants showed significant improvement on verbal memory, working memory, verbal fluency, attention	Brief Assessment of Cognition in Schizophrenia (Japanese version)	Small sample Level 3
Lipskaya-Velikovsky et al (2016) Israel	A pilot study investigating the effectiveness of a newly developed short term intervention programme, 'Occupational Connections'	Pre-post pilot study	10 people with schizophrenia	The intervention was structured to encourage development of the understanding and expansion of positive occupational experiences and engagement in occupations with personal and social meaning Focus on occupation-related needs and skills (reflecting its occupational orientation), with respect to each participant's unique interests, values, needs and experiences	The study group showed a greater tendency toward cognitive improvement, participation diversity, satisfaction, and enjoyment and participation intensity	Observed Tasks of Daily Living, Adult Subjective Assessment of Participation, Schizophrenia Quality of Life Scale, Positive and Negative Syndrome Scale, Letter–Number Sequencing Test Trail Making Test, Neurobehavioural Cognitive Status Examination Rey-Osterrieth, Complex figure test Category Fluency Test	Small sample Quota sampling Level 3
Wisenthal et al (2016) Canada	To evaluate the effectiveness of cognitive work hardening in preparing people with depression to return to work and identify key elements of the intervention	A single group pre-test–post-test study design (mixed method)	21 participants with depression	Intervention was provided in a simulated (office) work environment equipped with workstations, computers, software applications, and other resources typically used by a knowledge worker Techniques include: Education Roleplays Coaching, Goal setting	Work ability, fatigue, and depression severity significantly improved post-intervention	Work Ability Index Multidimensional Assessment of Fatigue Beck Depression Inventory II	Small sample No control group Level 3

Appendix 2. Original studies (Continued)

Vizzotto et al (2016) Brazil	To test the efficacy of the Occupational Goal Intervention method for the improvement patients	Pilot randomised controlled trial	25 patients with treatment resistant schizophrenia	Rehabilitation programme targeting executive functions using learning strategies to improve everyday functioning. Based on the Goal Management Training method developed by Levine et al (2000)	Significant statistical differences, favouring group in terms of improvement on the Behavioural Assessment of the Dysexecutive Syndrome test, both in sub test and the total score Improvements in executive functions were observed by families in various dimensions as measured by different subtests	The Direct Assessment of Functional Status The Independent Living Skills Survey Wechsler Abbreviated Intelligence Scale	Very small sample No control Level 3
Eklund et al (2017) Sweden	To evaluate the effectiveness of the 16-week Balancing Everyday Life programme, compared to care as usual, for people with mental illness in specialised and community based psychiatric services	Cluster randomised controlled design	133 participants and control group of 93	A group and activity-based lifestyle intervention, entailed active support, mainly standard occupational therapy, with a group-based programme (5–8 participants) consisting of 12 sessions, one session a week, and 2 booster sessions with 2-week intervals Themes for sessions: activity balance meaning and motivation healthy living work-related activities leisure and relaxation social activities	The Balancing Everyday Life group improved more than the care as usual group from baseline to 16 weeks on activity engagement, activity level and activity balance. The Balancing Everyday Life group also improved more on the secondary outcomes of symptom severity (P<0.018) and level of functioning (P<0.046) from baseline to 16 weeks, but not on wellbeing	Profiles of Occupational Engagement for People With Severe Mental Illness Global assessment of Functioning (GAF-S and GAF-F) Satisfaction with Daily Occupations	Large sample Control group smaller than intervention group Level 2

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RESEARCH ARTICLE

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The missing link-participants' perspectives on transfer from psychosocial interventional contexts to everyday community life: a qualitative synthesis of interventional studies

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Abstract

Background: The aim of this study was to illuminate participants' experiences with transfer in (1) Illness Management and Recovery (IMR); and (2) two programs based on peer support: Turning Points, and Learn to Tackle Anxiety and Depression (LTAD); and whether peer support within these programs influenced the process of transfer beyond the interventional context. Furthermore, we investigated participants' experiences with a community-based intervention [Individual Placement and Support (IPS)] to explore perspectives on mechanisms that may eliminate challenges in the transfer process.

Methods: The study was based on semi-structured interviews with participants with mental illness, from four different psychosocial interventions with and without peer support and across interventional settings. The material partly consists of secondary analyses of existing data sets of anonymised, transcribed interviews investigating participants' experience from two psychosocial interventions: Illness Management and Recovery (n = 15), and Individual Placement and Support (n = 12). Additionally, we conducted semi-structured interviews with persons who had participated in one of two peer-led programs: Turning Points and Learn How to Tackle Anxiety and Depression (n = 12). The analysis was guided by a hermeneutic-phenomenological approach to illuminate transfer processes and was based on the template method described by Nigel King.

Results: Applying a transfer perspective on rehabilitation interventions identified everyday life situations where capacities learned during the interventions were utilized and conditions were highlighted that promoted or hindered transfer. Experiential knowledge and peer-exchange made transferal pathways between the interventional context and everyday life. Illness intrusiveness and uncertainty, together with environmental obstacles, generated transferal gaps. Individualized support could partly address these gaps.

Conclusion: Findings from this qualitative study illuminate how peer-support in group-based rehabilitation interventions increased social functioning and developed better self-care strategies that can be transferred to daily life. Interventions situated in mental health settings, e.g. outpatient clinics, had limited impact on participation in broader community life. Advancing rehabilitation services in mental health may benefit from tailoring services to address

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illness fluctuation and combining group sessions with individualized support together with acknowledging and overcoming environmental obstacles.

Keywords: Rehabilitation, Recovery, Peer-support, Qualitative study, Learning, Self-management, Inclusion, Social psychiatry, Mental health

Background

Recovery, conceptualized as clinical recovery, encompassing symptom relief or remission and improved functioning, and personal recovery, referring to the process of rebuilding a satisfying and meaningful life, are the predominant goals of psychiatric rehabilitation [3, 9, 35, 36]. However, the effect of the well-known psychosocial interventions social skills training, psychoeducation, and Illness Management and Recovery (IMR) on functioning and personal recovery is unclear. Two systematic reviews from 2006 and 2008 [24, 32], found an effect of social skills training on functioning, but according to a Cochrane review from 2015 there was no significant difference between the effect of social skills training and active control groups [2]. In a Cochrane review from 2011, Xia et al. found an effect of psychoeducation on compliance and relapse prevention. A few studies included in the Cochrane review suggested a potential effect of psychoeducation on psychosocial functioning, but quality of evidence was rated as low [44]. Zou and colleagues reported similar findings in their systematic review of self-management educational programs, on relapses and prevention of re-hospitalizations. An effect on psychosocial functioning could not be confirmed, as the included studies produced conflicting results [45]. Furthermore, six RCTs testing the effect of IMR on functioning and personal recovery have yielded mixed findings [12, 14, 18, 25, 34, 39].

These interventions are based on the prerequisite that skills and knowledge acquired during the course can be transferred to everyday life beyond the interventional context, e.g. by home assignments [2, 30, 45]. However, it has been questioned whether skills learned in clinic-situated interventions can be generalized to the community [5]. Robert Lieberman described two decades ago that patients attending social skills training had difficulties generalizing skills acquired during the intervention to daily life and utilizing them outside the group [5, 19, 26]. The potential gap between clinic-based learning and the community is not unique to the psychiatric rehabilitation field. The concept of transfer stems from learning theory and refers to the process of transferring what is learned in one context to another context—to translate and apply knowledge and skills acquired during classroom-based training in real life situations [1, 17, 31].

Peer-support services (peer-support groups, peer workers) have become increasingly acknowledged in mental health sectors. In a qualitative study, Gillard and colleagues suggest that identification with a role model and building trusting relationships based on shared experiences are central mechanisms in peer-worker interventions, and these mechanisms may increase empowerment, self-efficacy and social functioning [16]. This could indicate that peer-support can potentially enhance the transfer process from interventions situated in mental health settings to everyday life in the community. Some qualitative studies of peer-workers, employed in mental health services have supported this assumption [10, 16, 37]. Storm et al. found that peer-support workers in community mental health centres often have the capacities to navigate mental health, social and primary sectors and have connections with networks in the community that can be helpful to the individual [37]. Similar findings was reported in a qualitive evaluation of a peer-led navigator program to individuals with severe mental illness [10]. Gillard et al. found in their study that peer-workers supported services users in attending activities outside mental health services, and thereby facilitated engagement in community [16].

In contrast to interventions situated in settings such as outpatient clinics and community mental health centres, is the vocational rehabilitation intervention Individual Placement and Support (IPS). The foundation of IPS is that vocational skills should not be trained in protected facilities. Instead, the person is supported directly in the workplace [7, 8]. IPS can be viewed as a response to the transfer gap as the intervention is not situated in a separate mental health environment, but in everyday life situations in the community.

The objective of this study was to explore participants' experiences with transfer in (1) Illness Management and Recovery (IMR); and (2) two programs based on peer support: Turning Points, and Learn to Tackle Anxiety and Depression (LTAD); and whether peer support within these programs influenced the process of transfer beyond the interventional context. Moreover, we investigated participants' experiences with an intervention situated in the community, [Individual Placement and Support (IPS)] in order to illuminate perspectives on mechanisms that may eliminate challenges in the transfer process.

Methods

The study was designed as a qualitative, explorative and comparative study consisting of semi-structured interviews derived from four different psychosocial interventions and varying settings. The interventions were IMR, two peer-led programs (Turning Points and LTAD) and IPS. Semi-structured interviews were applied as a data-collection method because it is an available and useful method to gain insights into people's lifeworld and learn about their perspectives regarding experiences in relation to the research topic [11, 28]. Semi-structured interviews have been applicable in a variety of contexts and research questions [27, 29, 43]. The semi structured outline in the interview guide, makes it unique among qualitative methods for the applicability it provides to explore the topic while remaining responsive to the participant [28].

The analysis was guided by a hermeneutic phenomenological approach and with a transfer lens embedded within the template method described by King [23].

Conceptual framework

Transfer stems from adult education where the purpose is to enhance job performance [17, 31]. Transfer goes beyond *acquisition* of knowledge and skills to involve *application* of knowledge and skills. For transfer to have occurred, learned behaviour must be generalized and maintained over a period [1].

Transfer theories highlight learning as a social process, suggesting that peers can play a crucial role in transfer. Peer exchange facilitates reflections and strengthens connectedness and awareness about one's knowledge. Input from peers can promote new opportunities to act. Peers contribute to a positive transfer climate, e.g. by impacting motivation for utilizing new knowledge and skills [1, 17].

Applying a transfer perspective on rehabilitation interventions may help to identify contexts and situations in daily life where acquired knowledge and skills are generalized, and pinpoint conditions that promote or hinder transfer. Nevertheless, fundamental differences between educational transfer and transfer in psychosocial interventions must be clarified. First, skills and strategies obtained during rehabilitation are personalized and suit the individuals' unique situations, rather than being a pre-defined curriculum. Second, the context is not an educational situation but a broader context of daily life.

Materials

The material partly consists of secondary analyses of existing data sets of anonymized, transcribed interviews investigating participants' experiences from two distinct interventions: IMR and IPS [15, 21]. Moreover, we conducted interviews with persons who participated in one of two peer-led programs: LTAD or Turning Points. The unified material for this qualitative study comprised 39 interviews.

The interventions' aims, contexts and methods are outlined in Table 1.

Interviews took place in surroundings according to the participants' preferences, e.g. their home or community mental health centre. Interviews were digitally recorded and transcribed verbatim. They lasted between 45 min and 2 ½ hours. Examples of questions from the interview guides are provided in the supplemental material.

Recruitment

Participants were recruited between 2015 and 2017. Most participants resided in Copenhagen, Denmark. Participants from the peer-led programs and from IMR received an oral or written invitation from the program's coordinators or the researcher who attended a group meeting. The last round focused on recruiting male participants from peer-support groups because they were under-represented after initial sampling. Participants from IPS were recruited to the study by self-referral at the IPS office [15]. Accordingly, the sampling strategy for this study on transfer was predominantly based on strategic sampling.

Method of analyses

Interviews were analysed based on King's template analysis strategy, which combines a horizontal analysis level with an inductive approach of individual variation [23]. This strategy was chosen because the research question necessitated applying an analysis strategy that explored the individual variation and compared the perspective of groups within a specific context and with a large set of qualitative data. The initial template focused on reducing the size of the material in order to condensate on the processes of potential transfer derived from the interventions [23].

Interviews were analysed separately for each intervention and then compared across the different interventions to identify the participants' perspectives on IMR versus peer-led programs. In Step 1, an initial template was produced with pre-defined topics: experiences linked to participation in the intervention, transfer to everyday life and experiences linked to recovery. Meaningful units were identified in the material, which was then sorted according to the defined topics. In Step 2, the meaningful units were condensed into categories and then gathered into sub-topics through an inductive approach (see example of coding in Table 2). In Step 3, the template was modified by gathering the sub-topics from the IMR study and from the peer-led programs. The volume of material was reduced. The sub-topics were read through again and, in an interactive process with the accompanying

Table 1 An overview of the interventions' aims and methods

	Illness management and recovery (IMR)	Individual placement and support (IPS)	Peer-led program 1 *(Turning points*[a]*)*	Peer-led program 2 *("Lean how to tackle anxiety and depression")*
Aim	To help people with severe mental illness, acquire knowledge and skills to better manage their illness as well as setting and achieving personal recovery goals	To help people with severe mental illness obtain competitive employment	Overarching aim is to assist people with mental illness in developing skills and strategies to pursue recovery	To help people with anxiety and depression acquire tools to gain control over their symptoms and to handle the challenges that accompany the illness. Additionally, to provide an opportunity where they can share experiences and thoughts with others in the same situation
Principles and/or methods	Curriculum-based psychoeducation, cognitive behavioural approaches to medication adherence, relapse prevention, social skills training and coping skills training	Focus on competitive employment, rapid job search, in-vivo support, benefit counselling, attention to client's preference, integration with mental health teams	Peer-exchange, self-directed learning. Equal and mutual support	Curriculum-based psychoeducation, coping skills training, role modelling, peer-exchange
Duration	Nine months	Unlimited	Approximately three months depending on the course	7 weeks
Peer-support	Yes—group-based sessions Sessions are led by mental health professionals (e.g. nurses)	No	Yes—group-based sessions Sessions are led by peer-workers	Yes—group-based sessions Sessions are led by peer-workers

[a] Turning Points contains a range of courses (designed to meet different needs among the participants)

Table 2 Coding process (Steps 1–2)

A prior defined theme	Subthemes	Categories (to Changes in social relationships)	Meaningful units (Dealing with social anxiety while being in the group)
Transfer to daily life	Changes in social relationships	Less anxiety in social situations	"Before that, I said no to every social get-together, or I came and went within a very short time. And that changed at least. The social anxiety actually became less because it was dealt with, by being in the group"
	Changes in perceptions of life	Re-engage in contact with family	."Every time I went home I was totally… (breathing deeply…) oh no, I can't go anymore, I've done something wrong, said something wrong, I can't… It was just like exercising—I can go next time. And I can stand it, I can handle it and the others are not a notch worse or better. And it was … it took a lot of training."
	Factors that enhance transfer	More confident in social settings	"So I'm not sitting there all the time and thinking, am I saying something wrong? Am I doing something wrong? Am I talking too much? … Those sorts of things are indirectly trained by being in these groups"
	Factors that impede transfer	Keeping in touch with peers from the IMR sessions	
	Mental vulnerability	Meeting new friends	
	A desert islands	Dare to open (talking about symptoms, future goals)	
	Interruptions of daily rhythms and routines	More outgoing	
	Managing day-to-day life with mental illness	More present and engaged when with others	

categories and meaningful units, were nuanced and re-organised into two central themes with four accompanying subthemes. In Step 4, interviews from IPS were analysed to find whether IPS could eliminate challenges in the application context identified in IMR and peer-led programs. First, an initial template with two themes, experiences of the IPS intervention and experiences of recovery, was used to identify meaningful units reflecting areas in the participants' lives that had changed during IPS. Second, the meaningful units identified in the interviews from IPS participants were mapped into three categories, each identifying mechanisms in the IPS intervention that supported change and utilization of skills in the participants' everyday lives. Third, in an iterative process with the transcribed interviews, and in comparison with the themes and subthemes derived from the interviews with participants from IMR and the peer-led programs, the three core categories were re-read and nuanced to a main theme reflecting how recovery is supported when the transfer challenges are avoided.

Results

Participants

The empirical basis consists of 39 interviews with participants from IMR, (n = 15), two peer-led programmes—LTAD and Turning Points (n = 12)—and from IPS (n = 12). Participant characteristics are presented in Table 3.

Findings

Two central and interacting themes were identified as illuminating the transfer processes from IMR and the peer-led programs to the participants' everyday lives in the community. The first theme, *individual experiential knowledge and peer -exchange build transferal pathways* refers to processes where knowledge and skills acquired during the sessions were applied in daily-life situations. The second theme, *Illness intrusiveness and overlooking environmental obstacles generate transferal gaps*, describes barriers and challenges in the transfer process, where acquired capacities were not utilized or where personal goals remained unrealized. The subthemes, *transfer to more profound relationships* and *transfer to better self-care,* describe distinct transfer pathways. The transferal gaps are described in two subthemes, *living with a chronic condition as an unreliable companion* and *facing real-world barriers*. The third theme emerged in IPS interviews*: A different path—the enabling role of individualized support,* with three subthemes, each reflecting enabling mechanisms; *"Having access to patient and flexible support through difficult times, "Someone to count on"*

Table 3 Demographic data

	Illness management and recovery	Individual placement and support	Peer-led programs[a]
Sex	6 men, 9 women	9 men, 3 women	4 men, 8 women
Age (range)	30–80	26–59	29–65
Diagnosis	Schizophrenia, Bipolar disorder	Schizophrenia, Bipolar disorder	Schizophrenia, Bipolar disorder, Recurrent depression, ADHD, Anxiety disorder
Supported living facilities	8	0	0
Work/internship/education	1	9	7

[a] Demographic data on participants from Turning Points and Learn how to Tackle Anxiety and Depression are merged and displayed in same columns

and "A natural foundation for utilizing skills and building confidence".

Figure 1 illustrates central themes and accompanying subthemes

Individual experiential knowledge and peer-exchange build transferal pathways

Participants described learning as a personal process, rather than acquisition of pre-defined knowledge and

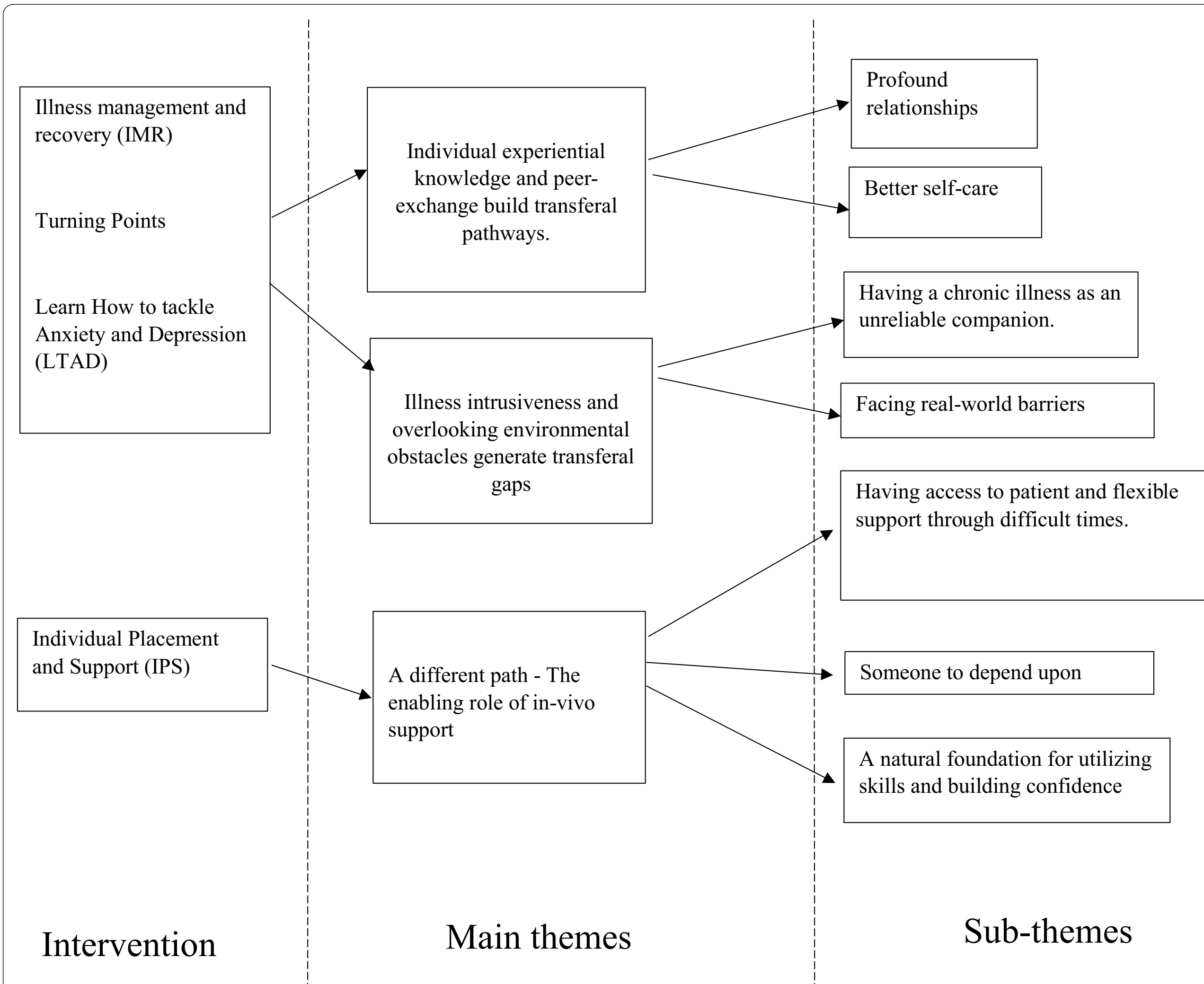

Fig. 1 An overview of main themes and subthemes

strategies. They experienced IMR and the two peer-led programs as courses where they learned about themselves and adopted new perspectives on life (Table 4, Q1 and Q2). Peer support was perceived in two ways. One, peer support was meeting other persons who struggled with mental health problems with whom one exchanged experiences and perspectives during the group sessions. For some participants, group sessions were arduous and anxiety-provoking; for others, they were a safe space (Table 4, Q7). Talking with peers about mental illness, daily matters and interests was highly valued among the participants. Several described that group conversations boosted self-confidence and gradually made them feel more present and relaxed in social situations. Two, peer support in the peer-led programs also covered peer workers, who were role models offering practical advice about how to deal with challenging daily situations (Table 4, Q6). Participants described the peer workers as someone to respect and to depend on. This required the peer workers being authentic—talking openly about their struggles with mental illness—and being a model for recovery and nurturing hope. Some participants experienced the peer workers as distanced and not sharing their own experiences; in one case, a participant perceived the peer worker as being too sick to be a role model (Table 4, Q8).

Transfer to more profound relationships

Most participants struggled with, for example, anxiety and self-contempt when engaging in social activities. A general feature of IMR and the peer-led programs was that group meetings became a safe arena to practice communication skills and build confidence that was transferred to other social situations in the participants' daily lives. Talking with peers, during the course had strengthened the participants' relationships with family and friends. They described becoming more comfortable and present in the company of their loved ones, becoming better at expressing their thoughts and becoming careful listeners (Table 4, Q3). However, participants also expressed some distance to family members who they felt could not fully understand the illness's intrusiveness, for example, not being able to eat out, or attend family gatherings.

Acquired social skills and confidence was also transferred to encounters with mental health professionals. Some participants, mainly from the peer-led programs, described encounters with professionals as being difficult, for example, to explain one's situation. Engaging with peers enhanced assertiveness and provided inspiration for new reflections and agendas used in meetings with therapists or councillors.

Transfer to better self-care

A unique feature of the peer-led programs was that participants learned self-care strategies that were transferred to everyday life. They utilized the strategies to make plans that complemented their energy levels, carefully choosing what arrangements to engage in (Table 4, Q4). One man from Turning Points highlighted the relief he felt from learning new ways to decline invitations without fear of disappointing friends and family. Others learned strategies to tackle anxiety attacks, such as choosing a seat close to an exit, strategies enabled them to attend concerts and lectures, activities that used to be impossible before joining the course. The peer workers' own experiences were the main source of learning strategies, which were often innovative and not typically "by the book". Participants could mirror themselves in the peers' narratives and found the advice and tips more useful than that from health care workers, which was often perceived as unrealistic or fit only for an ideal world. Participants greatly valued the peer workers' human touch. Two women from the peer-led programs said that the most important thing they had learned during the course was to go slowly, accept the bad days and to take care of themselves (Table 4, Q5).

Illness intrusiveness and overlooking environmental obstacles generate transferal gaps

Participants from IMR and the peer-led programs identified conditions that undermined transferring what they had learned during the course to everyday life. They struggled with disabilities that disrupted daily living and hampered opportunities to pursue personal goals. The inability to carry out everyday activities and do what people around them took for granted caused shame, guilt and feelings of worthlessness. Some did not perceive the group sessions as a learning situation per se, rather a breathing space and a haven, where they could share experiences with peers and meet understanding and acceptance (Table 4, Q9).

Participants had various reasons for attending the courses. Often, the need to share experiences and meet peers was greater than the need to learn new skills and strategies. Some women from LTAD described the content as "nothing new under the sun". Participants expressed a major shift from learning new strategies or voicing personal goals in the group and subsequently acting on them. The interventions had limited transfer to the broader domains of daily life, such as handling practical activities—e.g. shopping or ordering a taxi—work, education and joining community activities. The transferal gaps are described in two subthemes: *Living with chronic*

Table 4 Supporting quotes for themes and subthemes

	Quote nos.	
Individual experiential knowledge and peer-exchange build transferal pathways		
	Q1	*"In Turning Points, I learned to respect and take care of myself."* (Female participant 1, peer-led program)
	Q2	*"I feel like I'm getting some concepts on, in my own life. But not only do I get the concepts, I also get what it means to me and how we move on from here…"* (Female participant 2, peer-led program)
Transfer to more profound relationships	Q3	*"(Before) When I had guests, I could stay for three hours, then I had to go to bed. AND that changed anyway. The social anxiety and the general anxiety were reduced because there was some processing in being in the group."* (Male participant 2, IMR)
Transfer to better self-care	Q4	"*I probably use the action plan most, I think. As a tool* *When I need to do something, it is nice to have an action plan of when to do it and how much to do it and how to do it…* *I must prioritize my energy. Having a full-time job is plenty for me. But then I have two young children, and a wife and so it … and a family and friends and stuff like that. So, I will have to prioritize if I have an arrangement with my friends like I had yesterday for example when there was football, well I know how to do it but then I probably must be careful about plans just around that day, right? So, these are some things that one thinks about. So, I'm sure that I to some extent can live a normal life." (laughs)* (Male participant 1, peer led program)
	Q5	*"For me the most important point was … It is OK to relax… It's like… mmm… it's like a war where you step back and it's OK. Because then you can win next time."* (Female participant 4, peer-led program)
The role of peer-support in facilitating transfer	Q6	*"Every time I went home I was totally… (breathing deeply…) oh no, I can't go anymore, I've done something wrong, said something wrong, I can't… It was just like exercising—I can go next time. And I can stand it, I can handle it and the others are not a notch worse or better. And it was … it took a lot of training."* (Female participant 5, peer-led program)
	Q7	*"One of the peer workers. I sometimes sit and think, is it me you are describing or is it yourself? Which is fun, after all. And interesting. Also, because there is one here where I could ask her very specific questions. Where I could say, eh. now what if a lot of people invite you out in a week, then it will simply be too much. How do you handle it then?"* (Male participant2, peer-led program)
	Q8	"*The thing about it is that you want the teacher to be healthy. But also sick because you want to mirror yourself, but also to be healthy because they must show that the course helps. And if they are not healthy and they say that now is the fifth time I'm teaching here. Then you think. Hell!! Then it doesn't work! If you haven't recovered."* (Male participant 3, peer-led program)
Illness intrusiveness and overlooking environmental obstacles generate transferal gaps		
	Q9	*"I have a lot of guilt about the things that I can't do, and I think that, or I know, it is like that for many of us, you feel ineffective, useless and impossible, right? And you take that very personally. And then you learn that you can say a lot of it really isn't me who can't get it right, it is the symptoms that are there and a lot of others also have the same. The symptoms. They all go round believing that it is them who can't get themselves up from the chair. Where they sit. And then go over and do the dishes or something. They can't, and it feels very personal. When in fact, there are a lot of people who feel that way. That are struggling with that. So that's a symptom. And that means, I think, a great deal that you can throw some guilt away."* (Female participant 5, peer-led program)

Table 4 (continued)

	Quote nos.	
Living with chronic condition as an unreliable companion	Q10	*"But I have a melancholy side, which I think is probably because of the way I have lived my life, or relationships, or childhood or something else that makes me have such dark thoughts. Yes, it changes back and forth. I have fewer symptoms, but it still fills me up somehow. I think it would be nicer if I could do the things I feel like and the things I think I need. It can be buying Christmas presents or going to Christmas lunch or going to lectures or… Things like getting up and out the door. One day I do something and the next day I can't."* (Female participant 2, IMR)
	Q11	*"The group suffered from the fact that there were persons there who were very good at playing therapists. Now you just … you just have to do this, you just have to do that… why don't you, and no … now you have to … take a phone call and all that… and you sit and feel so bad that you can't even go to the bathroom, right? It is kind of, we must improve our situation, all the time. And it's not always possible."* (Female participant 5, peer-led program)
Facing real-life challenges	Q12	*"It can be a little bit… with people who are "healthy". Healthy in inverted commas, OK? Then you can be a little, oh they are looking at me. I'm such a… and so on… So, I withdraw and… keep a low profile. Not standing out in the crowd… But feel that I do that anyway. Like there's a big elephant in the room yelling, she's mentally ill, just look at her, right?"* (Female participant 6, peer-led program)
	Q13	*"I'm not going to complain … I've gotten a lot better. And quality of life has improved. But not working and being on sick leave… Then, it doesn't matter that much anyway … so I really must practice patting myself on the back. Because I still have to say, well, it doesn't matter … because I have no job."* (Male participant 3, peer-led program)
A different path—the enabling role of individualized support		
	Q14	*"It's very nice because it is in many ways a kind of open offer, which means that I actually have the freedom to act."* (Male participant 1, IPS)
	Q15	"*I am really happy with my employment specialist because he, he can accommodate me and my oddities and he helps and supports and so I am allowed to try some things myself … because … if I can then it is f***ing fine, that I can myself but when it is hard for me then he supports me in it."* (Female participant 1)
Having access to patient and flexible support through difficult times	Q16	*"When I'm not feeling well, I tend to isolate myself a bit. Take care of myself, in a way … and it is nice, when he (the employment specialist) sends me an SMS … just checking up, how are you? Finding out where I am … right now … and should there be more on the table … should we have more contact … should we have less … uhhh … is it because it's going well or is it because it is not going well … so yeah, find out where I am right now and what is needed."* (Female participant 1, IPS)
	Q17	*" When my husband left me… I felt like h… Well, we put it on hold, but we didn't give up … well, because, there were just a few months where I just didn't go out and look for jobs and these things, because I couldn't … uhhh … and it helped. I was very, very fond of her (the employment specialist)"* (Female participant 2 – IPS)
Someone to depend upon	Q18	*"The fact that I felt listened to and taken seriously and sometimes even received constructive criticism … also made me believe more in myself and therefore I also dared to do some more things. I think if I hadn't had the support from the employment specialist that I've had … then I don't think I would have dared to call those companies and ask … Can I send an unsolicited application and where should I send it? Because then I'd have been afraid of the rejection almost as soon as I introduced myself."* (Female participant 3- IPS)
	Q19	*"He (the employment specialist) has given me a different experience. When I call him and say there is a problem, well he takes it seriously … he tries to look at it and see if he can solve it. He calls around and he sets things in motion and in many cases, well it turns out he can do a whole lot of things … which many mental health professionals have not mentioned at all as an opportunity…"* (Male participant 3, IPS)

Table 4 (continued)

	Quote nos.	
A natural foundation for utilizing skills and building confidence	Q20	*"It (work) gives me some stability. I have problems with structure. It gives me some content … in my week … that I do something … it gives me … identity. … It gives me stability and I can combine it with the rest of my daily life … so I can have a normal week. So, I'm not just lying at home and lying on the bed. And that is important"* (Male participant 4 – IPS)
	Q21	*"I did go to college and I found out … I was actually really good at it … well … like getting As !!!! And I was both surprised and proud. And then I changed my education plan … because I found that there were some things … I was pretty good at them and I didn't know."* (Female participant 1, IPS)
	Q22	*"During the periods when I worked, it meant a lot. My health has improved … I have had fewer admissions … shorter admissions … less medication consumption uhhh so in general just an increase in my standard of living … so from the purely psychiatric point of view, but also a question that I … that in my daily life I feel better and I have better finances, I can do more things and some things like that."* (Male participant 2, IPS)

illness as an unreliable companion and *Facing real-world barriers.*

Living with chronic illness as an unreliable companion

Most participants struggled with unpredictable, fluctuating and intrusive symptoms; anxiety; hallucinations; and lack of impetus and energy, disrupting their everyday lives. The symptoms made them cancel plans, struggle with practical tasks, caused difficulties leaving their homes or enjoying interests. In general, participating in IMR or the peer-led programs did not alter the intrusive impact of their symptoms. Living with mental illness was like living with an erratic and unreliable companion (Table 4, Q10). Many described the process of making changes as arduous or anxiety provoking. Fear of failure prevented some participants from setting goals or trying new activities. Home assignments were perceived differently among the participants. For some, these assignments supported them in pursuing personal goals during the course, such as taking up new activities or altering morning routines. Others felt the assignments were an imposition. One woman criticized LTAD for assuming it was always possible to improve one's situation and that there should be constant progress. Overall, she agreed that one could actively work on improving the situation, but she also emphasized that this was not always possible (Table 4, Q11). Consequently, the process of transferring new capacities to the context of daily lives and putting actions behind words was often challenging and sometimes unfeasible.

Facing real-world barriers

Being detached from the community was a common experience among participants. They felt that they were living strange lives that were out of balance. Struggling with an invisible and disabling illness made the participants feel estranged from their loved ones and unaccepted in society (Table 4, Q12). Some had lost friends during the years of struggling with illness, leaving them isolated and lonely. A few experienced a vacuum after the course had ended. One woman compared the time after finishing LTAD to her childhood memories of the greyness and emptiness in the days after Christmas Eve. Activities, such as going to concerts, were challenging when one had to do it alone. One woman from IMR said that she felt like a desert island and that society saw her as an illness and not a human being.

Finding employment was a main goal for many participants. Attending the peer-led courses had inspired some participants to become peer workers themselves. Others expressed disappointment at not finding employment after they had completed the course (Table 4, Q13). Learning new strategies and gaining more personal confidence was not enough to obtain work as many participants lacked work experience or professional training due to years of struggling with mental illness. Receiving social benefits had considerable consequences for the participants' daily lives, for example, not being able to repay loans or take vacations.

The interviews revealed that skills and knowledge could be transferred to some extent from the interventional context to the participants' daily lives in the community, and that peer support facilitated this. However, the findings also identified transferal gaps. Utilizing new strategies and pursing personal goals were hampered by the intrusive and disruptive nature of the mental illness and environmental conditions such as loneliness, financial matters, and labor-market demands. In the next section, these findings are compared with the experiences of participants from IPS, where there are no transfer challenges.

A different path—the enabling role of individualized support

Three enabling mechanisms in individualized support emerged in the interviews with IPS participants. Firstly, the continuous and flexible nature of the support offered by the employment specialist (ES) enabled participants to pursue vocational goals whilst dealing with relapses, struggling with symptoms etc (Table 4, Q14 and Q15). Secondly, not being alone while searching for jobs, and having someone who believed in them and supporting them encouraged the participants to take risks and face challenges in the job searching process. Thirdly, utilizing skills and knowledge while searching for jobs, working or studying built confidence and new capacities. Hence, engaging in real-life activities was a natural foundation for personal growth and recovery. The three mechanisms identified in the IPS interviews are captured in the subthemes; "*Having access to patient and flexible support through difficult times*" and "*Someone to count on*" and "A natural foundation for utilizing skills and building confidence".

Having access to patient and flexible support through difficult times

The IPS's approach of flexibility and unlimited time allowed participants to apply for jobs when it suited them. Participants valued the continuity of the ESs support—that they were there for them, through hospitalizations, worsening illness and life-events. They experienced the ESs being sensitive to their needs, offering the type of support appropriate for the situation (Table 4, Q16). This also involved postponing job searching, if necessary (Table 4, Q17). Participants experienced the support as highly individualized and appropriate for their specific needs, enabling them to pursue long-term goals such as completing an education or obtaining work.

Someone to depend on

Participants described job searching as a demanding process with both good and bad experiences. They highlighted the core ingredient in IPS: to have someone "on their side", someone who they could relied on (Table 4, Q18). The type of support depended on the participants' situation. It included having the opportunity to share both successes and frustrations, update CVs, and search for jobs together as well as receiving an SMS with a "good luck" greeting on the first day of a new job. The ES's ability to navigate the complex welfare system, providing access to social services, was highly valued among the participants. So was the experience of being met as person, rather than as a patient or client. Participants valued the ES allowing them take initiatives and responsibility, and face challenges, for example, when contacting potential employers. The relationship with the ES boosted participants' confidence and determination to take chances and try out new situations while applying for work (Table 4, Q17).

A natural foundation for utilizing skills and building confidence

Being a student or employee promoted a positive self-image, an identity beyond mental illness, an outlook of a better future, and a more solid economic basis from which to enjoy life (Table 4, Q20 and Q21). Some participants described a "domino effect": engaging in education or work influenced other aspects of their daily life, such as taking up hobbies, improving daily routine or doing more daily activities such as cooking meals (Table 4, Q19). Others described strategies and tips that they had adopted from the ES that enhanced their self-care in terms of balancing activity and rest.

Discussion

In this study, we analysed interviews with participants from IMR and two peer-led programs, to identify whether and, if so, how transfer from the interventional context to daily life occurred and how peer support influenced transfer processes. Transfer gaps and transfer paths co-existed in most participants' narratives. They experienced group sessions as a safe place to practice social skills, build confidence and reconnect to goals and dreams. The group became a personal learning forum where agendas and aspirations—combating loneliness, finding interests and re-engaging in work, education or community activities—were nurtured and strengthened during the course. The capacities acquired during the course could to some extent be transferred to social situations beyond the learning contexts, allowing the participants to become more present, relaxed and confident around their loved ones, and more assertive in encounters with professionals. Transfer theories highlight that similarities between contexts increase the possibility of transfer [1]. This might explain why transfer related to social functioning was the most prominent theme across interviews, while transfer connected to functioning in other areas, for example, finding a job or going grocery shopping, generally was not identified. Several participants had difficulties in their daily lives, for example, when doing daily tasks, finding work, or engaging in community activities, that remained unchanged after the course had ended. All participants described how intrusive and disruptive symptoms impacted their lives, their relationships, their opportunities for living well and doing what they wanted. In our study, illness management did possibly relieve, but certainly not eliminate the disabling impact of symptoms. This finding may modify a central rationale behind self-management interventions, that better illness management leads to living more functional lives [6, 30, 45] and add perspectives to why effectiveness of psychoeducational programs on psychosocial functioning might be hard to determine in the systematic reviews by Xia et al. and Zou et al. [44, 45]. Notably, in the peer-led programs, learning new self-care strategies, e.g. prioritizing energy or practicing self-compassion, was highly valued and could be transferred to the participants' daily lives. Interestingly, strategies and skills obtained during the course were not from the curriculum but from the peer-workers' personal experiences. Transfer theories underline that transfer can be enhanced by the teacher's insight and experiences regarding the student's context. Accordingly, examples and practical and concrete explanations facilitate the transfer process [1]. That could explain why many participants found the strategies and skills learned from peers more useful and applicable than the advice and input from mental health professionals. This has been addressed in a review by Davidson and colleagues, suggesting that peers introduce new ways of using experiential knowledge in negotiating day-to-day life, not only with the illness but also with its social consequences such as poverty and stigma [13].

Living with disability and vulnerability was perceived as a lonely experience for the interviewees, who felt disabled and estranged. Many described feeling more comfortable among their peers than among so-called healthy people and experienced the group as a place for connectedness difficult to experience elsewhere. This corresponds with findings by Van Langen et al., where participants in IMR groups described feeling deviant and alienated in their own social environment. They described the group sessions as a refuge from daily life, where they felt safe, accepted and understood [42].

The "Missing Link" in our study refers to the gaps in the transfer processes and may be related to putting too great an emphasis on the individual process of recovery during the interventions. Our study shows that having hopes, aspirations and confidence may not be sufficient to ensure recovery if the person's environment does not provide opportunities for continuous support, inclusion and community participation. It has been suggested that social aspects of recovery have been neglected [22, 33, 41]. Recovery is both an individual <u>and</u> a social process. Borg and Karlson describe important aspects of recovery as being supported and valued for the person one is, engaging in meaningful activities and being welcomed and accepted by other people and in various social settings, overcoming stigma and no longer being discriminated against due to one's health condition [22]. Recovery unfolds in environments and situations that provide opportunities for nurture, challenges and recognition. Hence, recovery is not only an individual matter, it highly depends on the person's network, access to support and opportunities in the community. In contrast, the participants in our study often felt alienated, deviant and isolated in the community. Correspondingly, in a study including 27 countries, Thornicroft found that among participants negative discrimination was experienced by 47% when making or keeping friends, by 29% when finding a job, and by 29% in keeping a job [40].

In IPS interviews, we found three enabling mechanisms of individualized support: the unlimited time and flexible support, having someone to depend upon, and real-world activities as arenas for personal growth and recovery. To some extent in-vivo support addresses some of the gaps embedded in the missing link. First, the support was tailored to the participants taking their life situation into account; the intensity, duration, and type of support was planned and delivered in close collaboration with the participants. Many participants stressed the importance of being met as whole persons with vulnerabilities and strengths. Correspondingly, in a qualitive study with IPS participants in Sweden, Areberg et.al. found that having someone on one's side—someone who validates ones wishes and needs—and having opportunities for utilizing one's own skills and competences brought hope and meaning to the process of searching for work [4].

Implication for clinical practice

Group sessions can build dreams, goals, aspirations and self-growth and thereby a motivational source in the recovery process. Our findings underline the necessity of providing such forums in recovery-oriented services; they also highlight the group sessions' shortcomings because the skills and confidence gained during the course to support recovery in the broader aspect of daily life and community participation are difficult to apply in other contexts. Clinicians and policy makers should be aware of this transferal gap. Our findings show how manifestation of mental illness can shape a daily life dominated by long-term disability and fluctuating invasive problems, and that psychiatric disabilities are often experienced as shameful and deviant. This raises the question of whether an underlying assumption of constant progress in rehabilitation services may put an unintentional pressure and risk of self-blame on the service user. Our findings identify a need to broaden approaches and pay more attention to the social sides of recovery when developing and advancing psychosocial rehabilitation services. First, there seem to be possible benefits of combining group-based interventions with individualized support. Second, more attention should be paid to the person's own environment, for example, by creating opportunities for participation and enhancing places and communities that foster inclusion and connectedness.

Strengths and limitation

This study applies secondary analysis of data from two previous qualitative studies, investigating participants' experience of recovery during IMR and IPS, respectively [15, 21]. The research questions and methodology were compatible with our study, which made it partially possible to analyse the material in a transfer perspective [20, 38]. The interview method provided insights into the participants' experiences with the interventions and enabled new understandings of whether and how there was a transfer from the interventional setting to everyday life. The researcher was sensitive about data being embedded in different contexts [20, 38]. Since secondary and original researchers were employed in the same institution, it was possible to provide additional information about the background and clarify any questions regarding the context [38]. Secondary analysis has limitations. First, it is not possible to recruit participants consistently until saturation has been reached. Hence, the sample needs to be sufficiently large. Although patterns became clear across interviews, there is a possibility that adding more interviews would have generated new informative data and more nuances of the findings. Second, member checking was not possible. The secondary researcher could not question the informants or conduct second interviews. We aimed to overcome this limitation by discussing the findings with an advisory board of mental health service users, who served as a source of validation [38].

The recruitment strategy favoured participants who were either participating in the intervention at the time of interview or who had completed the course. This question the transferability of the results as the perspectives of participants who dropped out during the interventions are not represented in this study. Applying a theoretical framework with a priori defined themes may have led to central themes in the interviews important to the participants and their recovery being overlooked. However, we attempted to make the codes as open as possible to capture the essence in interviews related to the study question.

Conclusions

Our findings highlight the gaps and paths between obtaining new knowledge and skills during group-based rehabilitation interventions, IMR and peer-support groups and applying and utilizing these capacities in the community. Group sessions have advantages regarding enhancing motivation and strengthening social skills and strategies for self-care. Experiential knowledge and sense of connectedness in peer support increases the transfer process. However, overlooking mental illness intrusiveness and uncertainty, and the environmental obstacles generates transferal gaps between interventional context and everyday life in community. Group sessions have shortcomings when it comes to enabling participation in, community life, work and education, and in carrying out. practical activities. Our results suggest that individualized support can partly counter the challenges identified in the transferal gap, providing the support is authentic, flexible and tailored to the person's needs and situation. Importantly, our findings show a need to address the social aspects of recovery in order to advance and increase the opportunities for participation in the community as well as in work and education if individuals struggling with mental illness are to be supported successfully in their recovery. Consequently, future interventional studies in the field of psychiatric rehabilitation should address structural barriers for social inclusion and community participation that people with mental illness face. This includes a closer scrutiny on physical and social attributes in the individual's environment, such as places, neighbourhood and presences of other people, and on underlying subtle processes embedded in the person's community, such as social interactions, cultural meanings and shared values. In this context, and in the view of the results in this study, more research on environmental enhancements and accesses to community resources, for supporting recovery and promoting health and wellbeing is warranted.

Abbreviations

IMR: Illness management and recovery; IPS: Individual placement and support; LTAD: Learn how to tackle anxiety and depression.

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Authors' contributions

SB developed the study's design, conducted interviews with participants from the peer-led interventions, data analysis and drafted the manuscript. LFE developed the study's design, applied for funding, interpreted data and provided intellectual and editorial supervision. TM developed the study's design, contributed to data analysis, interpreted data and provided intellectual and editorial supervision. The final manuscript has been read and approved by all authors. All authors read and approved the final manuscript.

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Availability of data and materials
The datasets analysed in this study are not publicly available, due to Danish law that prohibit data sharing.

Declarations

Ethics approval and consent to participate
The study was registered with the Danish Data Protection Agency (j.no. RHP-2017-009). The IMR and IPS studies are registered with the Danish Ethics Committee (j.no. H-1-2010 and S-2015-2000-163). According to Danish Law, no ethical approval from the Ethics Committee was required for the present study because no biomedical intervention took place. All participants gave informed, written consent. All direct reference to the individuals has been anonymised.

Consent for publication
Yes.

Competing interests
The authors have no competing interests.

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Trials

STUDY PROTOCOL

Meaningful Activities and Recovery (MA&R): the effect of a novel rehabilitation intervention among persons with psychiatric disabilities on activity engagement—study protocol for a randomized controlled trial

Siv Therese Bogevik Bjørkedal[1*], Ulrika Bejerholm[2], Lene Falgaard Eplov[1] and Tom Møller[3]

Abstract

Background: Engagement in activities meaningful to the individual may support the process of recovery in those with mental illness. Persons with psychiatric disabilities may reduce their engagement in meaningful activities to various degrees with possible fluctuations over time. We hypothesized that activity engagement can be altered when opportunities and support are offered at an individual and a group peer-based level. Evidence is lacking regarding mental health interventions that enable engagement in meaningful activities, and powered effect studies are warranted.

Methods: We propose an 8-month combined individual and group peer-based intervention, Meaningful Activities and Recovery (MA&R), and a study protocol for a multicentre two-armed parallel randomized controlled trial (RCT). The trial investigates the effects of MA&R in community mental health centres in Copenhagen and municipality services in Denmark. The trial will comprise 128 participants with psychiatric disabilities who will be randomized to one of two groups: (1) MA&R in addition to standard mental healthcare or (2) standard mental healthcare alone. The primary outcome is self-reported activity engagement, measured by Profiles of Engagement in People with Severe Mental Illness. Secondary outcomes are recovery, functioning and quality of life. Data will be collected at baseline and at follow-up at the end of the intervention.

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Discussion: This study adds new knowledge to a field with limited evidence, i.e. the clinical effectiveness of rehabilitation interventions among people with psychiatric disabilities, directly targeting activity engagement. The pragmatic design, regarding in- and exclusion criteria and settings, may allow assessment of the intervention's effect under real-life conditions. The randomization, adequate power and fidelity monitoring allow testing of the intervention's efficacy. The multicentre study design increases the potential for implementation in various mental health settings if the findings are positive. As the nature of the intervention does not permit blinding of the participants or staff, it may increase the risk of expectancy and performance bias. This must be considered when interpreting the findings.

Trial registration: ClinicalTrials.gov NCT03963245. Registered on 29 May 2019

Keywords: Mental illness, Occupational therapy, Peer support, Rehabilitation, Recovery, Mental health, Wellbeing, Disability

Background

Psychiatric disabilities refer to inabilities and impairments when performing activities that the individual wishes or needs to perform in order to pursue life goals and fulfil social roles [1]. According to WHO's International Classification of Functioning (ICF), performing activities is pivotal in enabling participation in major life areas, such as work, education, relationships, leisure and self-care [2]. ICF conceptualizes disability as a dynamic interaction between an individual's health condition and contextual factors in that person's life situation, e.g. coping style, social network and work. Substantial evidence shows that psychiatric disability is influenced by a complex interplay of symptoms, personal factors such as self-efficacy, and environmental conditions such as stigma or access to support [3–6]. Qualitative studies [7–14] in persons living with psychiatric disabilities have found that activity engagement is often reduced [7–9, 13, 14]. Simple activities, such as getting out of bed or leaving the house, can be arduous or sometimes impossible [8, 13, 14]. In some situations, inactivity may be therapeutic [8, 14]. In others, it may be detrimental, with isolation, preoccupation with thoughts, and lack of energy [9]. Inertia may be related to the illness leading to losses, for example, loss of identity, social status and close relationships; loss of future hopes and dreams; and loss of opportunities for work, education and material goods [8–10]. Living with mental illness can lead to isolation and fear. The risk of being overwhelmed, experiencing worsening of symptoms and facing stigma are aspects considered when engaging in daily activities [7, 9, 12, 15]. Thus, lack of activity engagement seems to be a key dysfunction related to psychiatric disability.

Observational studies suggest that the extent varies to which persons with psychiatric disabilities are engaged in activities. Higher levels of activities are associated with fewer mental health symptoms and better cognitive functioning, sense of coherence, self-mastery, empowerment and belief in one's own work potential [16–19]. In RCT designs, one trial investigating the effectiveness of supported employment found that the intervention group increased their levels of activity engagement over 18 months [20]. In another, participants mapped their everyday activities, identified personal goals and planned strategies for change. They found this intervention more effective than care as usual regarding functioning and activity engagement [21]. However, there is currently a lack of evidence-based interventions that directly focus on activity engagement, and knowledge is lacking about how meaningful activity engagement can be supported as a crucial part of the recovery process for persons with mental illness [22–26]. This study builds on the evidence that occupational therapists (OTs) in mental health aim to enable participation in activities that are meaningful to the individual [27–29]. Moreover, we seek to imbed strategies of peer support since systematic reviews and meta-analysis suggest that peer support may foster hope, empowerment and social inclusion [30–33]. Hence, our study promotes peer support to enhance activity engagement by offering persons with psychiatric disabilities support to become active agents in their recovery process, to identify strengths and to break out of inertia and isolation [34]. The objective of the present study is to investigate an 8-month multifaceted intervention based on documented evidence from various psychiatric and occupational-based approaches. We aim to enable activity engagement in a diverse population of individuals with various psychiatric diagnoses and across healthcare and municipality settings.

Objectives

This paper introduces a new rehabilitation intervention named Meaningful Activities and Recovery (MA&R) and presents a study protocol for a multicentre, two-arm parallel RCT to compare the effect of two interventions: (1) MA&R in addition to standard mental healthcare and (2) standard mental healthcare. This study protocol is reported according to the Standard Protocol Items:

Recommendations for Interventional Trials (SPIRIT) 2013 statement [35, 36], and the study design is guided by the Consolidated Standards of Reporting Trials (CONSORT) criteria [37] for randomized trials of non-pharmacological treatment.

The primary objective of this RCT is to determine whether MA&R in addition to standard mental healthcare is more effective than standard mental healthcare alone regarding activity engagement (POES-S) [38, 39] in a sample of individuals living with psychiatric disabilities. The intervention is being tested in addition to standard mental healthcare as it is an add-on to usual care.

The second objective of this study is to evaluate whether MA&R in addition to standard mental healthcare is more effective than standard mental healthcare alone regarding outcomes related to activity engagement, e.g. functioning, personal recovery and quality of life [40–42].

Methods

Settings and participants

The study is conducted in Copenhagen Research Centre for Mental Health, CORE. The MA&R intervention is delivered in the five different sites where eligible participants will be recruited. The largest sites are two community mental health centres (CMHCs), situated in the Copenhagen Mental Health Center. The CMHCs offer outpatient services to persons with mental illness who live in central Copenhagen. The three other sites are municipality services in Copenhagen, Odense and Svendborg. The municipality services include rehabilitation services and drop-in centres for persons with mental health issues, and/or psychiatric disabilities, and are selected due to their contact with the study's target group.

Eligible participants are identified by any professional at the respective sites or by self-referral (Fig. 1). The participant must be aged 18 years or older, have a psychiatric disability assessed by a researcher using the Mini-ICF Rating for Limitations of Activities and Participation in Psychological Disorders (Mini- ICF-APP) [43], be diagnosed with a mental disorder and provide informed consent. Persons ineligible for study participation include persons diagnosed with dementia, those with alcohol or substance abuse as a primary diagnosis or abuse that inhibits attendance at MA&R sessions, those with a

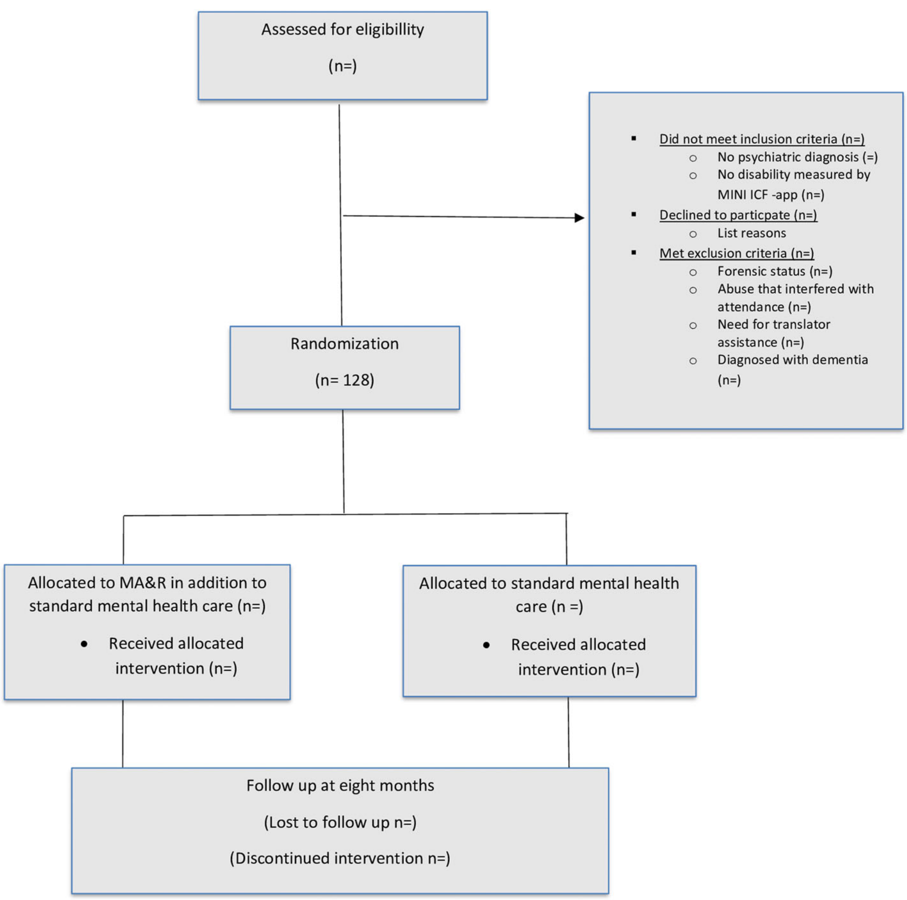

Fig. 1 Displays the flow of participants from recruitment to study end

forensic psychiatric status, those who require translator assistance (unable to speak Danish) or those who refuse to sign informed consent.

Trial management

The principal investigator (LFE), co-investigators (TM and UB) and researcher (SB) communicate regularly through telephone conversations, e-mails or in person about preparation, revision and agreement of final protocol, publication of study papers and reviewing the progress of the study. The principal investigator (LFE) meets every 2 weeks with the researcher (SB) and research coordinator (BKE) to monitor trial conduct, i.e. closely reviewing the recruitment progress, data completeness and quality, contractual issues with the individual sites, training of counsellors and outcome assessors and budget administration. The senior researcher and assistant professor at the University of Copenhagen (JMK) make an annual external assessment of the study progress.

Recruitment, consent and allocation to interventions

The enrolment period is planned to last 24 months: September 2018 to August 2020. Staff at each site screen individuals who meet the inclusion criteria and refer potential participants to the study. The researcher attends staff meetings to inform members about the project. Posters to encourage self-referral are displayed at the sites, e.g. in the reception areas in the community mental health centres. The researcher meets the candidates at the community mental health centre or in the candidate's home. Oral and written information about the trial is provided. If the person decides to participate in the study, an informed consent form is signed. After baseline data are obtained, the participants are randomly assigned to either the control (standard mental healthcare) or experimental group (MA&R + standard mental healthcare) with a 1:1 allocation using the randomization module in REDCap (Research Electronic Data Capture) [44, 45]. The randomization sequence was generated by a researcher employed outside the research team and entered to RedCap. The randomization is stratified by sex. Varying block sizes, unknown to the research team, are used. To ensure concealment, the randomization schedule is stored away from the research team and the block sizes are not disclosed. The allocation is performed by the researcher, who informs the participants and the counsellors and who assigns participants to the interventions.

Intervention

Meaningful Activities and Recovery

MA&R is a rehabilitation intervention tailored to persons with psychiatric disabilities, developed by the authors in collaboration with OTs and peer workers from community mental health centres. MA&R aims to enable and support meaningful activity engagement. The iterative process of testing and retesting the programme in loops with continuous feedback from service users, OTs and peer workers informed the programme delivery method, e.g. introducing one-to-one sessions and support as an alternative to home assignments, and presenting information in a manner sensitive to cognitive difficulties among participants. Additionally, the authors conducted a qualitative study that investigated how peer support and individualized support enhanced activity engagement in the everyday lives of persons with psychiatric disabilities participating in psychosocial interventions (to be submitted). Results from that study were integrated into the process of developing MA&R. Accordingly, MA&R is a multifaceted intervention where crucial elements to enable activity engagement include individualized support in the participant's natural environment, peer workers and peer support in groups.

MA&R consists of 11 group sessions and 11 one-to-one sessions, which take place alternately. MA&R is delivered by a peer worker and an OT. In addition to the planned sessions, the participants are offered individualized support to engage in meaningful activities. The MA&R is a manualized intervention, with a workbook developed for the participants to support learning and personal exploration. MA&R utilized various methods such as didactic presentations, peer exchange, direct experiences with activities and personal exploration. The MA&R contains two courses: MA&R I and MA&R II, which complement each other. In MA&R I, the participants can explore and identify meaningful activities, while MA&R II supports anchoring new activities and habits in everyday life.

MA&R I consists of six group sessions and five one-to-one sessions and lasts for 7 weeks. Group sessions take place weekly and typically last 90 min. The group session is followed by a one-on-one session, which takes place one to 4 days after the group session.

MA&R II consists of five group sessions and six one-on-one sessions and lasts for approximately 5 months. In group sessions, participants are introduced to strategies for enabling activity engagement, e.g. making gradual changes by setting sub-goals. In addition to the planned sessions, the participants are offered individualized support in engaging in activities or initiating new activities.

Table 1 provides an overview of the themes and content in MA&R. In the community mental health centres, MA&R is delivered by the first author (STB), who is an OT, together with a peer worker. In the municipalities, MA&R is delivered by an OT or a social worker and a peer worker. The first author provides training and

Table 1 Overview of themes, delivery mode (group-based or one-to-one sessions) and aims of the sessions in modules 1 and 2 in MA&R

Topic	Delivery mode[1,2]	Aim
MA&R 1: *Overall aim: Learning about the role of meaningful activities in wellbeing and recovery and identifying meaningful activities in everyday life*		
Introduction to MA&R I	One-to-one session	▪ Learn about the structure and content in MA&R I ▪ Exchange mutual expectations of the course ▪ Talk about learning styles
Flow	Group session One-to-one session	▪ Emphasis on the main message in MA&R: what you do in daily life matters ▪ Learning about health and flow theory ▪ Identify activities associated with the experience of flow and/or wellbeing
Activity patterns in daily life	Group session One-to-one session	▪ Learning about activities and activity patterns ▪ Mapping own activities ▪ Identifying activities, routines, habits or contexts that influence well-being
Recovery	Group session One-to-one session	▪ Learning about recovery and how meaningful activities and day-to-day actions matter in the recovery process ▪ Learning about recovery and how it may unfold in daily life ▪ Abolish taboos and promote hope
Telling personal stories through an activity perspective	Group session One-to-one session	▪ Preparing narratives at the next group session ▪ Identify values, interests and personal resources through storytelling ▪ To tell one's story in a safe forum, and to help each other explore personal resources and unique features
Photo-voice: picturing the future	Group session One-to-one session	▪ Consolidating MA&R I sessions by showing photos of meaningful activities in daily life
MA&R 2: *Overall aim: To anchor meaningful activities, habits and routines in daily life*		
Introduction to MA&R II	One-to-one session	▪ Learn about the structure and content in MA&R II ▪ Exchange of mutual expectations of the course
The PEO model (person-environment-occupation) Mapping opportunities for activity engagement	Group session One-to-one session	▪ Learning about a problem-solving method to identify opportunities and barriers for meaningful activities ▪ Identifying strengths, opportunities and resources that can enable activity engagement by applying the PEO model
One step at a time	Group session One-to-one session	▪ Learning about habit changing and goal setting, e.g. by setting sub-goals ▪ Discussion about setting sub-goals, e.g. by trying to apply the goal staircase
More energy in daily life	Group session One-to-one session	▪ Learning strategies to balance activities and rest ▪ Planning and prioritizing energy-consuming activities ▪ Discussing and tailoring strategies to daily life
Better overview of daily life	Group session One-to-one session	▪ Learning about cognitive difficulties and personal strategies to tackle them ▪ Discussion and tailoring strategies to daily life
Photovoice: meaningful activities now and in the future	Group session One-to-one session (optional)	▪ Take photos of meaningful activities in relation to recovery or activity engagement ▪ Consolidating and evaluating MA&R II by showing photos of meaningful activities taken by the participants. Dialogue about maintain activity engagement during difficult periods in life
Catching up	One-to-one session	▪ Boost strategies and/or motivation for activity engagement, and clarify need for support

[1]In the sessions, a variety of methods are utilized: didactic presentations, dialogue, peer exchange, storytelling, worksheets and photovoice
[2]In addition to the planned sessions, participants are offered individualized support to initiate or sustain activity engagement. Examples of support are practical help, companionship when trying out new activities, looking for new opportunities for activities in the community, etc.

supervision of the OTs, social workers and peer workers in the municipalities. Fidelity will be monitored once per course with the MA&R Fidelity Scale, an instrument developed for the purpose. The evaluation will be done by external evaluators.

Standard mental healthcare

Standard mental healthcare in the CMCHs includes appointments with a psychiatrist, psychologist and/or care manager, in addition to psychoeducation, social skills training, peer-run recovery groups and relational support. Standard mental healthcare in the municipalities includes supported accommodation, drop-in centres, social activities, creative activities, self-esteem groups, peer services, skills-training, individualized support in activities of daily living (ADL) and relational support. Concomitant care, such as additional psychological counselling and National Acupuncture Detoxification Association (NADA), is permitted during the trial.

Modification and adherence

The intervention can be discontinued if the participants withdraw consent, or the investigators identify harms caused by the intervention, e.g. if the participants report mental health deterioration or symptom worsening due to participation. Adherence to the intervention is monitored and improved by allowing different parts to be delivered in a flexible manner, e.g. scheduling the one-to-one sessions according to the participant's preferences. To enhance attendance, an SMS is sent as a reminder the same day as group sessions are held.

Outcome measures

This study aims to investigate the effectiveness of MA&R on activity engagement and associated health outcomes, functioning, personal recovery and quality of life. The primary and secondary outcomes will be assessed twice, before randomization (baseline) and after intervention (follow-up, t_1). Sociodemographic data and clinical measures are obtained at baseline, and harm measures are obtained at follow-up. Assessment methods are self-report questionnaires. Functioning will be rated by an assessor at baseline and register data obtained to identify harms.

Baseline measures

Sociodemographic data and clinical measures Enrolled participants are asked to report their age, personal identification number (CPR number), housing status, educational level, marital status, number of children, income status, and information about psychiatric diagnoses and alcohol or substance abuse. Disability is assessed by the researcher using Mini-ICF Rating for Limitations of Activities and Participation in Psychological Disorders (Mini-ICF-APP), an observer rating instrument.

The MINI-ICF-App has been found to have substantial internal consistency (Cronbach $\alpha = 0.869–0.912$), good test-retest (ICC 0.832) and interrater (ICC 0.886) reliability [43]. The MINI-ICF-App assesses capacity limitation within 13 domains, e.g. self-care, structuring tasks and relationships, and gives a total score within the range of 0 and 52, where a higher value indicates a more severe degree of disability.

Primary outcome

Changes in activity engagement between baseline and t_1 are measured using the self-report version of the Profiles of Occupational Engagement in people with Severe Mental Illness (POES-S) [39], an instrument developed to assess time-use patterns of activity performance and the extent to which these patterns are characterized by engagement. POES-S consists of two parts: a 24- h, yesterday time-use diary sheet and a questionnaire with nine items reflecting activity engagement, e.g. daily rhythm of activity and rest, variety of activities POES-S gives a total score between 9 and 36, a higher score indicates greater activity engagement. POES-S has high internal consistency, $\alpha = 0.85$ [21, 38, 39]. Changes in activity engagement will be assessed by comparison of the POES-S mean score with standard deviation (SD) and median at post-intervention (t_1) between the experimental and control groups.

Secondary outcomes

Changes in functioning between baseline and t_1 are measured with WHODAS 2.0 12-item version, a self-administered instrument consisting of 12 items derived from the WHODAS 2.0 36-item version [42, 46]. Disabilities within 12 domains of functioning, e.g. household responsibilities and community activities, are summarized to a total score between 12 and 60, where higher values indicate higher levels of disability. Scores on WHODAS 2.0 12-item version account for 85% of the variance in scores on the full 36-item version. The psychometric properties of WHODAS 2.0 12-item version are good with high internal consistency and excellent convergent validity [47, 48]. We also use the six subscales in the WHODAS 2.0 36-item version as an exploratory outcome measure. Changes in functioning will be assessed by comparison of WHODAS 2.0 12-item mean score with SD and median at post-intervention (t_1) between the experimental and control groups. In addition, a mean score will be calculated for each of WHODAS 2.0 six subscales and compared between the experimental and the control groups at post-intervention (t_1). Changes in personal recovery between baseline and t_1 are measured with the Questionnaire about Process of Recovery (QPR) [40]. QPR measures the aspects of the personal recovery process, e.g. sense of agency and hope. In this study, we use the QPR 15-item version, which gives a total score between 0 and 70; higher scores are indicative of recovery. The QPR 15-item version has high internal consistency, test-retest reliability and convergent validity [40]. Changes in personal recovery will be assessed by comparison of QPR mean scores with SD and median at post-intervention (t_1) between the experimental and control groups. Changes in quality of life between baseline and t_1 are measured by the Manchester Short Assessment of Quality of Life (MANSA) [41]. MANSA contains 16 questions related to quality of life, e.g. satisfaction with life, job and financial situation. The sum score is 12–84, higher values indicate a greater quality of life. MANSA has shown reasonable psychometric properties in respect to concurrent validity, construct validity and internal consistency [41]. Changes in quality of life will be assessed by comparison of MANSA mean score with SD and median at post-intervention ($t1$) between the experimental and control groups. The Clinical Global Impression – Severity of Illness Scale (CGI-S) is used to measure the severity of mental illness. In this study, we use a self-reported version of CGI-S where the participants are asked to rate the severity of their current mental symptoms on a 7-point Likert scale from 1 (equal to no signs of mental illness) to 7 (the worst the disease has ever been). Studies show that CGI-S self-reported scores correlate with clinician-assessed scores ($r = 0.34$) [49]. Changes in severity of mental illness are assessed by comparison of CGI-S score mean, with SD and median at post-intervention (t_1) between the experimental group and control group. Changes in health-related quality of life are measured with EuroQol (EQ-5D), a validated instrument that covers five dimensions: mobility, self-care, usual activities, depression/anxiety and pain, and includes a VAS scale of 0–100, with a higher score indicating a better health status. The EQ-5D can be transformed into an index score [50]. Changes in health-related quality of life will be assessed by comparison of EQ-5D mean scores with SD and median at post-intervention (t_1) between the experimental group and control group.

Blinding

Due to the nature of this trial's intervention, the mental health professionals at the sites, the staff delivering MA&R and the participants cannot be blinded to the intervention allocation. The research assistant who collects follow-up data is blinded, and the participants are instructed not to disclose the allocation status to the research assistant. An employee outside the research team will extract data from REDCap on study completion to two separate Excel sheets, and group allocation will be coded with A and B to ensure blinding of the researcher while analysing data, drawing conclusions and writing up reports.

Data collection methods and management

The first author (STB) collects all data at baseline and is trained in using the MINI-ICF-app Social functioning scale through training videos provided by Hogrefe (https://www.hogrefe.co.uk/shop/mini-icf-app-social-functioning-scale.html). The participants can respond to the questionnaire in one of three ways: the questionnaire can be sent as an e-mail containing a link to answer the questions online; the participants can complete the questionnaire in a pen-and-paper format, or the participant can respond to the questionnaires with assistance from the researcher. How the participants respond to the questionnaire is listed in REDCap. Attendance at MA&R sessions is registered in the intervention-arm by the MA&R mentors facilitating the course. Follow-up data are obtained using the same questionnaires as used at baseline. Questionnaires are sent to all participants, including those who have decided to withdraw from the intervention, unless they have withdrawn their consent to participate in the study. The participants are reminded or prompted to complete the questionnaires through personal contact (SMS or phone call). To enhance adherence to the trial, participants are assisted if they wish by a research assistant at follow-up and the follow-up schedule is as flexible as possible to minimize the burden on the participants. Study data are collected and stored using REDCap, an electronic data capture tool hosted at the Capital Region of Denmark. REDCap is a secure, web-based software platform designed to support data capture for research studies [44, 45]. Access to data requires a two-step unique log-in system and is granted to researchers and staff affiliated with the project. A trial audit will not be conducted due to lack of funding. All physical data material (signed consent forms, case report forms and questionnaires) is stored in locked facilities. Table 2 shows an overview of the data collection.

Data quality will be promoted through a variety of procedures. First, monthly data monitoring is conducted by the research coordinator (BKE) for data completeness and verification of data, e.g. personal identification number. Missing or invalid data are reported directly to the researcher (SB). Secondly, REDCap has functions designed to detect missing data and certain errors in data, e.g. invalid values. Thirdly, a subset of case report forms and questionnaires will be selected by a researcher outside the research team to check accurate data entry prior to analysis. Lastly, final data control will be performed before analysis by the research coordinator. Participant files are stored for up to 10 years after study completion.

Sample size

The sample size is calculated based on the primary hypothesis to detect a minimal but clinically significant difference between the intervention group and the control group on POES-S (increased engagement in meaningful activities). In a recent RCT testing, the intervention Balancing Everyday Life (BEL) in a similar population as that in this study, Eklund et al. found a small effect of 1.4 points measured on POES-S ($d = 0.27$) [21]. As MA&R has a more comprehensive format (in terms of duration and costs) than BEL, the clinically significant difference between the study groups is set to 3 points, corresponding to a moderate effect size (Cohens $d = 0.5$). Based on the BEL trial, we assume the standard deviation in the study population to be 6. To achieve a statistical power of 80% and a significance level of 5%, a total of 128 participants must be included in this study; 64 in each group to detect this difference.

Table 2 Schedule of data collection during the MA&R study period

Time point	Enrolment	Baseline	Randomization	Intervention period	Eight months follow-up
Eligibility screening	x				
Informed consent	x				
Allocation			x		
Register sheets for attendance in MA&R					
Self-assessment data					
- POES-S		x			x
- WHODAS 2.0		x			x
- QPR		x			x
- MANSA		x			x
- Euro-QoL		x			x
- CGI-S		x			x
CRF including MINI ICF Social Functioning Scale		x			
Registry data					x

CRF case report form

Statistical methods

The main outcome measure is activity engagement, measured by POES-S. To test the research hypothesis, the differences between the intervention group and the control group will be analysed using ANOVA to determine the statistical significance. Effect sizes to judge clinical relevance will be calculated by Cohen's *d*.

In accordance with the intention-to-treat principles, "multiple multivariate imputations" will be used and all co-variates of supposed prognostic significance will be used to impute a distribution of missing data.

The continuous power measurements will be analysed with a repeated measurement model in mixed model analyses with unstructured variance. The prerequisite for using this analysis and for the use of multiple imputations is that data are missing at random or data missing completely at random as opposed to non-ignorable non-response. This distinction is important as repeated measurements and multiple imputations are both models based on a statistical estimation of non-existent responses, and the prerequisites for this estimation must be met for the analyses to be valid.

Whether the prerequisites for using repeated measurement and multiple imputations are present will be analysed by performing a drop-out analysis. Significant prognostic characteristics of the non-follow-up participants will be compared with those of the participants remaining in the trial. Variables where there is a difference between participants and non-participants will be included as co-variables in the analyses. Data analyses will be based on the intention-to-treat principle. Data from all participants will be included corresponding to the group to which they have been allocated. As a supplementary analysis, we will carry out per-protocol where complete cases will be analysed.

Differences between the intervention group and the control group regarding secondary outcomes will be analysed applying the same statistical methods because all outcome variables are continuous.

A detailed statistical analysis plan will be prepared before initiating analysis and uploaded at clinicaltrials.gov

Monitoring

Based on trials with similar interventions, such as BEL, we do not anticipate any adverse risks or reactions to MA&R. Harms will be identified as unfavourable changes in psychiatric symptoms, hospitalizations (somatic and psychiatric) and deaths (all causes) and will be evaluated at follow-up. Data on psychiatric symptoms will be obtained through questionnaires (GCI-S), while data on hospitalizations and deaths will be obtained from The Danish National Patient Registry and The Cause of Death Register. Adverse events will be reported in trial publications, to the sites, sponsors and the ethics committees. Unexpected harms are collected during the study period, through e-mail, telephone or face-to-face communication with participants in the intervention arm and counsellors. Examples of unanticipated adverse events attributed to the intervention and patient population can be elevated levels of stress, e.g. irritability or self-blame, and will be reported to the researcher by the participant or mental health staff. Harms are discussed in the research group at the bi-weekly meetings. Unexpected adverse events will be reported to the sites and ethics committees and in trial publications.

Dissemination policy

The results will be published in at least one article in a peer-reviewed scientific journal. The results will also be published in a PhD dissertation and in professional journals, after scientific publication. Positive, negative and inclusive results will be published. Results from the research project will also be presented at scientific conferences. Authorship is determined by the Vancouver criteria (http://www.icmje.org).

Discussion

Psychiatric disabilities are prevalent across a range of mental health disorders and can entail tremendous costs for both the individual and society [3–5, 51–53]. Persons with mental illness may experience daily life as a vicious circle of lack of energy, inertia and isolation [9, 10]. Engagement in activities perceived as meaningful can play a crucial part in the recovery process [24, 26, 34]. However, evidence is scarce of how to support persons with psychiatric disabilities in re-engaging and sustaining meaningful activity engagement. This necessitates interventions that directly target activity engagement. This study aims to investigate the effectiveness of a novel rehabilitation intervention designed to enable engagement in activities that are meaningful in the participants' lives. Evidence-based interventions targeting activity engagement are few, and this trial will contribute with new knowledge about rehabilitation interventions among individuals with psychiatric disabilities. The CONSORT 2010 statement [37] and the SPIRIT 2013 guidelines [35, 36] informed the study design, and the trial has a sample size sufficiently large to detect a moderate effect size of MA&R if it exists. This is a multicentre study, with sites in community mental health centres and municipalities, which may increase the potential for implementation in various mental health settings, if the findings are positive. The pragmatic design of the trial, regarding in- and exclusion criteria and settings, enables assessment of the intervention's effect under real-life conditions. Patients and clinicians were involved in designing, pilot testing and giving the feedback that informed the development of MA&R. Research questions and outcome measures were discussed in the research group consisting of clinicians and researchers, with input from mental health professionals. The rationale for choosing the outcome measure is due to its major clinical relevance. The burden of participating in the research was carefully assessed by pilot testing the questionnaires among lay members, which narrowed down the number of outcome measures.

Nevertheless, this study has methodological weaknesses. First, it is not possible to blind the participants and the professionals to allocation. The researcher who developed MA&R is involved in delivering the interventions in the community mental health centres. This increases the risk of performance and expectancy bias and will be considered when discussing the results of the trial. Second, it has not been possible to stratify pr. site, but this potential confounding factor will be considered during stages of the statistical analyses. Third, MA&R is delivered as an add-on to standard mental healthcare treatment/service. Participants are encouraged to continue to use the standard mental health services, but no data exist on the quantity of participants' mental health service use.

Moreover, the focus of the trial is on the effect of the intervention but does not incorporate participants' perspectives on the impact of the intervention. Therefore, a qualitative study of MA&R will be conducted if additional funding is generated. We plan to conduct health economic analysis, using data from EQ-5D, if further funding is obtained.

Trial status

The trial was launched in September 2018 and is currently in the recruitment phase. Recruitment is anticipated to be completed by 30 August 2020. The data collection period is planned to end in February 2021. This is protocol version No 4, from 19 November 2019.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s13063-020-04722-3.

Additional file 1:. Data category and information.

Abbreviations

BEL: Balancing Everyday Life; CRF: Case rapport form; CONSORT: Consolidated Standards of Reporting Trials; CORE: Copenhagen Research Center for Mental Health; EQ-5D: EuroQol; GDPR: General Data Protection Regulation; ICF: International Classification of Functioning, Disability and Health; MANSA: Manchester Short Assessment of Quality of Life; MA&R: Meaningful Activities and Recovery; MINI-ICF-App: Mini-ICF Rating for Limitations of Activities and Participation in Psychological Disorders; Self-rapport version – POES-S : Profiles of Occupational Engagement in people with Severe Mental Illness; QPR: Questionnaire about Process of Recovery; SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials; CGI-S: Clinical Global Impression – Severity of Illness Scale; WHODAS 2.0 12: WHO Disability Assessment Schedule 2.0; WHO: World Health Organization

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Authors' contributions

STBB drafted the manuscript and participated in planning the intervention and designing the study. LFE and TM developed the trial, participated in the planning and designing the intervention and in the study design, and read and critically revised the manuscript. UB critically read and revised the manuscript. All authors read, improved and approved the final manuscript.

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The University College of Copenhagen partially financed the researcher's salary during the development of MA&R. The municipalities of Copenhagen, Svendborg and Odense partly financed the salary of the staff delivering the intervention. The funding parties do not take part in decisions regarding designing and conducting the study.

Availability of data and materials
It is not possible to obtain access to the final trial dataset as data sharing is not permitted by Danish law.

Ethics approval and consent to participate
The trial is approved by the regional committee of ethics (H-18017307) and the Danish Data Protection Agency (VD-2018-299, I-Suite nr: 6543). The protocol is registered at http://www.clinicaltrials.gov/ (Protocol Record NCT 03963245). Protocol amendments that may affect the conduct of the study will be submitted to Clinical Trials. Participants' data are collected, stored and processed following GPDR. The project is carried out following the Helsinki Declaration. Written, informed consent is obtained before the participants are included in the research project and data are collected. The researcher emphasizes that participation is voluntary and that at any time, the participants may withdraw from participating in the trial without any consequences for them or the mental health services they receive or may need in the future. Because the MA&R trial is not assumed to be associated with any risk of harm, according to the investigators of similar interventions, a data monitoring committee will not be appointed, nor will any interim analysis be performed.
Regarding ancillary and post-trial care, there is free access to treatment in Denmark; accordingly, participants in this study have free access to the necessary treatment.

Consent for publication
Not applicable

Competing interests
The authors declare that they have no competing interest.

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Publisher's Note

Meaningful Activities and Recovery (MA&R). A peer co-led occupational therapy intervention for people with psychiatric disabilities. Results from a randomized controlled trial.

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Abstract

Background: Activity and participation is pivotal for health and wellbeing. Limited evidence exists on how to support people with mental illness in participating in activities in everyday life.

Aim: To investigate the effectiveness of Meaningful Activities and Recovery (MA&R), a peer co-led occupational therapy intervention, on activity engagement, functioning, quality of life and personal recovery.

Methods: A single-blinded multi center RCT, with 139 participants from seven community and municipally mental health services. They were randomly assigned to 1) MA&R and standard mental health care or 2) standard mental health care. MA&R consisted of 11 group-sessions, 11 individual sessions, and support to engage in activities. Outcomes were measured at baseline and post intervention follow up.

Results: MA&R was delivered with high fidelity and with low study attrition (17,8 %). MA&R did not demonstrate superiority to standard mental health care, as intention-to treat analysis revealed no significant differences between the groups in activity engagement, nor harms or any of the other secondary outcomes.

Conclusion: MA&R appear to be feasible and acceptable. Potential effects might have been hampered by circumstances due to COVID 19. Research on activity engagement is warranted, to refine MA&R, before investigating its effectiveness in future studies.

The trial was registered on May 29th, 2019, at ClinicalTrials.gov NCT03963245

Keywords: Rehabilitation, peer-support, community mental health, evaluation

Introduction

Psychiatric disabilities occur when a mental health condition, together with obstacles in the environment inhibit individuals in performing everyday activities and participating in major life areas, for instance work or civic life.(1,2) Psychiatric disabilities can have overwhelming effects and disseminate into loss of daily structures, social status, identities and financial security. (3–6) Stigma attached to mental illness, means that people with psychiatric disabilities often face negative prejudices and avoidances, leading to social exclusion. (7–10) Time use surveys show that persons with mental illness spend more time alone, on quiet activities such as sleeping or watching TV, or on "doing nothing", and less time on work, household and enjoyable activities, than people without mental illness. (11–14) Activity engagement is fundamental for people`s health and wellbeing. (15–18) It captures individuals` subjective experiences of their involvement in activities of everyday life, how they occupy their time, where they are and whom they are with. It comprises actual doing (activity performance), reflections and meaning making of the experiences. Activity engagement have been linked to empowerment, locus of control, quality of life, and recovery processes (14,19–26) Occupational therapists in mental health seek to enable activity engagement, by enhancing people`s abilities and opportunities or by modifying the environment. (27) There is a need to develop and evaluate interventions, that target activity engagement, to strengthen the evidence base informing occupational therapy practice in mental health. (28–30) To address this, two time use interventions, Action over Inertia (AOI) (31,32) and Balance in Everyday Life (BEL) have been developed. BEL was tested for its effectiveness in an RCT, showing a significant effect on activity engagement. (33) Both interventions are group based (AOI can also be delivered as a workbook), which enhance important processes of re-valuing meaningful activities and for personal growth.(32,34,35) Yet, results from a qualitative synthesis showed that group format may not be ideal for enabling activity engagement in the wider life in the community. (36) Hence, finding new ways to address activity engagement is warranted. It has been proposed that bridging together lived experiences of mental illness and recovery, provided by peer-workers, and professional knowledge about the health promoting effects of activity engagement, holds potential to strengthen recovery-oriented practices in mental health. (32,37)

We developed Meaningful Activities and Recovery (MA&R), a peer co-led occupational therapy intervention, to support activity engagement and personal recovery. MA&R was investigated in a multi-center, single blinded randomized controlled trial (RCT). The RCT compared the effectiveness of two interventions: 1) MA&R in addition to standard mental health care and 2) standard mental health care. We hypothesized that MA&R, in addition to standard mental health care, would be more effective regarding activity engagement, measured on Profiles of Occupational Engagement in people with Severe Mental Illness-Self-rapport version (POES-S) (38) than standard mental health care alone. Hence, activity engagement was the primary outcome in this study. We hypothesized that MA&R would be more effective in improving functioning, personal recovery, and quality of life.

Methods

The RCT methodology is detailed described in a protocol paper by Bjørkedal et al. (39) No amendments were made, after the paper was published.

Participants

Eligible participants were 1) 18 years or older, 2) had a psychiatric diagnosis (or more than one), 3) could speak and understand Danish, 4) had a psychiatric disability, assessed by the primary researcher using MINI ICF Rating for limitation of Activities and Participation in Psychological Disorders (MINI-ICF-APP) (40) and 5) provided informed consent. Individuals who received forensic psychiatric treatment or had dementia could not participate in the study.

Setting

The study was conducted in 3 community mental health centers (CMHCs) in Copenhagen, 3 activity and social support centers (ASSCs) in Copenhagen and Svendborg, and one rehabilitation team in Odense. In Denmark, public mental health services are organized into two sectors: the CMCHs, that offer **treatment** to patients, through in – and outpatient services (41) and municipal mental health services, that offer **social and rehabilitation services**. (42) Both sectors serve citizens with mental illness in their catchment area. The sectors complement each other; therefore, participants often received services from both sectors. MA&R was co-led by occupational therapists and peer-workers employed at the sites (the rehabilitation team and two ASSCs), or by first author, who is an occupational therapist and a peer-worker, employed in the project (the CMCHs and one ASSC)

Interventions

MA&R

MA&R consists of 11 group - and 11 one to one sessions, taking place alternately. Participants are also offered individual support to engage in activities. MA&R is organized into two modules: MA&R I, with two weekly sessions focused on exploring and recognizing meaningful activities, and MA&R II with two monthly sessions allowing participants to engage in new meaningful activities in their own pace. MA&R is manualized. The curriculum focuses on health, recovery, and strategies for engaging in activities.

MA&R was delivered in locations in the partaking sites, the participant`s homes and sometimes in the community (e.g., fitness centers). The professionals delivering MA&R received training in the manuals and methods prior to the intervention, (3 hours workshop, and individual preparation) and supervision (1,5 hours x 6, in addition to ad hoc supervision if needed) during the intervention period. Supervision was given by first author, who developed MA&R.

Standard mental health care

The treatment in CMCHs was delivered according to the Flexible Assertive Community Treatment- model (the F-ACT model), a flexible multidisciplinary treatment model, where patients are provided intensive support when needed, and when the condition has been stabilized, the treatment is downgraded back to standard individual case management. (43) In addition to F-ACT, standard mental health care included services shown in figure 1.

Standard mental health care offered at the ASSCs were relational support (with staff and peers), café and social happenings, group activities and vocational rehabilitation. The rehabilitation team offered individual and group-based rehabilitation services, depending on the person`s needs and preferences. (Figure 1)

PLEASE INSERT FIGURE 1 ABOUT HERE

Data collection and outcome measures

Sociodemographic and clinical data, i.e., personal identification number and self-reported information about psychiatric diagnosis were obtained at enrollment in the trial. The MINI-ICF-APP was used to measure psychiatric disabilities. It is an observer rated instrument, consisting of a semi-structured interview guide covering 13 domains of capacity limitations, e.g., self-care and relationships. It gives a total score between 0 and 52. Higher value indicates a more severe psychiatric disability. (40)

Outcomes were measured twice, at baseline and at the end of the MA&R intervention.

For measuring activity engagement, the primary outcome in this study, the POES-S (38) was chosen. POES-S was developed on the basis of time-use studies of persons with schizophrenia (14,44) and has been in psychometric tests (44–46) found to be a valid and reliable instrument for measuring activity engagement. Secondary and exploratory outcomes were functioning, personal recovery and quality of life. An overview of outcomes and description of the outcome measures used in the trial, is found in table 1.

PLEASE INSERT TABLE 1 ABOUT HERE

Harms

Number of admissions and bed days (psychiatric and somatic), number of deaths and causes, and The Clinical Global Impression – Severity of Illness Scale (CGI-S) were obtained at post intervention follow up.

Sample size

A sample size calculation on primary and secondary outcomes was performed before the trial was initiated. Based on findings in the BEL trial, (33) which measured activity engagement with POES-S in a population like ours, we assumed the standard deviation in the population to be 6. To achieve a statistical power of 80 % and a significance level of 5 %, we calculated that 128 participants should be included in the study, 64 in each group, to detect a difference of 3 points, corresponding to a moderate effect size, on the POES-S.

Randomization

The participants were randomly assigned (1:1) to either MA&R in addition to standard mental health care or standard health care alone. The primary researcher, who enrolled participants and collected the baseline data, performed randomization, using REDCap (Research Electronic Data Capture) (47,48) The allocation sequence was stratified by sex, and used varying block sizes. It was generated by a staff member external to the research team and stored away from the team during the study period, to keep the allocation sequence unknown to the research team.

Blinding

Researchers were blinded to the participants allocation, at the timepoints of data collection and during analysis and writing the conclusion of the study. It was not possible to blind participants or the professionals to the intervention allocation. The research assistant, helping some of the participants filling out questionnaire as post intervention follow up, was blinded to the participants intervention allocation. Participants were instructed, not to reveal this to the research assistant, prior to their meeting. Researchers were blinded to allocation, during primary statistical analysis and while writing the conclusion of the study.

Fidelity assessment

A MA&R fidelity scale was developed to assess the delivery of MA&R in all sites. The scale applies individual structured interviews with the occupational therapist and the peer-worker delivering MA&R and focus group interviews with participants. All participants in MA&R were invited to participate in the fidelity assessments. Interviews were performed at the end of the intervention, by an external evaluator. The MA&R fidelity scale covers six major components: staffing, organization, group sessions, individual sessions, contact and individual support, all considered as essential for successful delivery of MA&R. The scale ranges from 0 to 41. Higher scores indicate higher degree of fidelity in the delivery of MA&R

Statistical methods

The analysis was based on the principle, “intention to treat”. Baseline variables were calculated as means for continuous variables (age, level of disability etc.) and as proportions for categorical (education level, diagnosis etc.) and dichotomous variables (sex, presence or absence of alcohol or substance abuse etc.) To test for differences between the intervention group and control group at baseline, chi^2 test was applied for categorical variables and t-test for independent groups was applied for ordinal/continuous variables. All primary and secondary outcomes were calculated and presented as mean scores with standard errors (SE) at baseline and post intervention. Differences in means and proportions was presented with a 95% confidence interval and a p-value. The two sides significant level for statistical tests were 5%. Differences between the intervention group and control group was analyzed using ANOVA to determine statistical significance. Multiple multivariate imputation was used, to handle missing values. All co-variate of supposed prognostic significance, (variables that were theoretical associated with the outcome, and variables that were predicted for missing data), were applied to impute a distribution of missing data.(49) The IBM SPSS Statistic version 10, for Windows was used for the statistical analysis.

Post hoc, we performed two additional analysis on

1. Within group changes, by comparing post intervention assessments to baseline in the intervention group and the control group, respectively, using paired t-test for statistical significance.

2. Differences in treatment effects, when MA&R was delivered under "normal conditions" and when MA&R was delivered under the COVID 19 pandemic. Participants were divided in two subsets: those who had completed post intervention follow up assessment before the COVID 19 lockdown, on the 12th of March 2020, and those who had completed post intervention follow up assessment during the COVID 19 lockdown. Within these two subsets, differences between the intervention group and the control group were analyzed, using the t-test for independent samples.

Modifications due to the COVID-19 pandemic

As shown in the timeline, (supplementary material) the trial was partly conducted during the COVID-19 pandemic. In Denmark, there was a lockdown, the 12th of March 2020. The ongoing MA&R groups (n=2) were put on hold and re-started in early June 2020, where the lockdown was re-placed with restrictions in the community. The pandemic did not directly affect the conduction of the RCT, as the trial adhered to the recruitment, randomization and data collection procedures described in the protocol. (39) The COVID 19 restrictions affected the interventional context, namely restricting opportunities for engaging in activities. This impacted intervention delivery. Thus, we undertook a subgroup analysis, examining the between group-differences among the subset of participants who had completed follow up assessments, before the COVID 19 lockdown, and the subset of participants who had completed follow up during the COVID 19 pandemic (lockdown and restrictions).

Ethics
The trial was conducted in accordance with the Helsinki Declaration. It was approved by the regional committee of ethics (H-18017307) and the Danish Data Protection Agency (VD-2018-299, I-suite nr: 6543). The study protocol is registered at http://www.clinicaltrials.gov/ (Protocol Record NCT 03963245). Participants' data were collected, stored, and processed following General Data Protection Regulation (GPDR). All participants have given informed, written consent for their data to be used in the study.

Results
Participant flow
Between September 2018 and August 2020, 139 participants were enrolled in the study and randomly allocated to MA&R in addition to standard mental health care (n=70) or standard mental health care alone (n=69). After randomization, 3 participants declined to participate in MA&R and 9 participants discontinued the intervention. Post intervention assessments were conducted between April 2019 and June 2021. 113 participants filled out questionnaires, providing data to at least the primary outcome. 26 participants were lost to follow up. No significant differences were found between responders and non-responders, in age, sex, educational level, functioning measured with MINI ICF-APP, or any of the baseline measures. A flow chart is depicted in figure 2.

PLEASE INSERT FIGURE 2 ABOUT HERE

Baseline data
71 women, and 68 men were included. Participants` mean age were around 43. Most were single, did not have children and lived alone. Many were either unemployed or received early retirement pension. Schizophrenia spectrum disorders were the most frequent reported diagnosis. The mean MINI-ICF-APP Score, in both groups indicated moderate grade of disability. No statistical differences were found between groups, in respect to demographic, clinical measures or baseline measures. Hence, the random allocation was equally balanced with no significant differences between groups. A detailed description of characteristics of the study sample, can be found in table 2.

PLEASE INSERT TABLE 2 ABOUT HERE

Each site recruited between 5 and 19 participants and conducted one or two MA&R groups. More participants (about 60 %) were recruited from the CMCHs then from the other sites. Between September 2018 and May 2021, a total of 10 MA&R groups were conducted, all completed. As beforementioned, the MA&R groups, conducted between March 2020 and May 2021, were influenced by the COVID 19 restrictions. Fidelity assessments were conducted for all MA&R groups. The fidelity scores showed good or optimal fidelity to MA&R. Fidelity scores for each recruitment site are presented in supplementary material.

Among the 67 participants starting in MA&R, 14 participants (20 %) attended between 0 and 10 sessions, 33 participants attended (49,3 %) between 11 and 19 sessions, and 20 participants (29 %) attended between 20 to 22 sessions. In average, participants attended about 15 sessions (SD: 5,7), corresponding to a mean of 7 group sessions and 8 one-on one sessions. A total of 40 participants (corresponding to 59 % of the participants starting MA&R) received individual support, in addition to attending the planned sessions. Among those who received individual support, each participant had on average 2,8 encounters (SD 2) with either the occupational therapist or the peer-worker.

Intention-to treat analysis showed that at post-intervention follow up, there were no significant difference between the intervention group and the control group, on the primary outcome activity engagement. As shown in table 3, we found a non-significant difference of 1,14 point (95% CI: 3,37, -1,09, p=0,315) in favor of the intervention group. No significant differences between groups were found in functioning, personal recovery, or quality of life (table 3). For the safety measures, no differences between groups were found in psychiatric admissions or bed days, or in somatic admissions or bed days, as shown in supplementary material

Post hoc analysis, showed that both intervention group and control grouped improved over time in activity engagement and in quality of life, measured by MANSA. Both groups improved in functioning, measured by WHODAS 2.0 36 items, but when measured by WHODAS 2.0 12 items, only improvement in the control group was significant. Control group had significant improvements in the *getting along* domain, and the *household* domain. Both intervention group and control group, improved in the *participation* domain. Only intervention group improved in personal recovery. No improvements were found in health-related quality of life, in any of the groups. (Table 3)

In comparison of the subsets of participants completing post intervention follow ups, before and after the COVID 19 lock down, we found a between group difference of 2,8-point score favoring the intervention group, (p=0,064) before the COVID lock down, and almost no difference, during the lock down. (Table 4)

PLEASE INSERT TABLE 3 ABOUT HERE

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Discussion

We hypothesized that MA&R would increase activity engagement among persons with psychiatric disabilities, and that MA&R when offered in addition to standard mental healthcare would be more effective than standard mental healthcare alone. Findings did not confirm this hypothesis. MA&R was not superior to the services offered in standard mental health care, when it came to enabling activity engagement, supporting recovery, promoting functioning or quality of life.

This is the first trial, to our knowledge, to evaluate the effectiveness of a peer co-led occupational therapy intervention. Our results diverge from the study by Eklund et al, who found an effect of BEL, which is an intervention with similarities to MA&R, both being focused on everyday activities, and have a group-based format. (33) Contrary to our trial, BEL was better than standard mental health care on several outcomes related to doing, such as activity engagement and functioning. Although MA&R and BEL have many similarities, there are also differences in the interventions` content and delivery. BEL utilizes home assignments to allow strategies for activity goals discussed during group meeting, to be practiced in real life conditions. In MA&R, participants were offered individual support, and home assignments were only applied, if the participant asked for it. This may have been a critical component, lacking in our intervention, however qualitative studies performed with participants from BEL, did not mention home practice as important. (34,35) In a study by Lund and colleagues, participants highlighted sense of belonging and mutual understanding in the group, as crucial for engaging in BEL. (35) MA&R had a mixed format, consisting of group sessions and individual sessions. This may have put less emphasis on developing group dynamics, to facilitate social and personal change processes. (50) Addressing the context is critical for interpreting the findings in this study. Contextual factors refer to anything beyond the intervention, that may hinder or facilitate it`s implantations or effects.(51) In contrast to the BEL study, MA&R was evaluated in community mental health centers, where treatment was delivered according to the F-ACT model. Participants in both groups had access to peer-support, either in group interventions and/or by peer-workers employed at the sites. Hence, core ingredients in MA&R, individual support, and peer-support were present in the control group too. One thing, making MA&R unique, compared to usual mental health care, was the opportunity for individual support offered to the participants, to engage in activities of their own choice, in the community. As mentioned, the trial was partly performed during COVID 19 and the restrictions impaired some of our stipulated change mechanisms, for instance providing access to opportunities for activities in the community. Hence, we questioned whether the null findings could be attributed to the restrictions during the pandemic. Post hoc analysis suggested that MA&R might have been better than standard mental health services before the COVID-19 lockdown, but not during. Interestingly, the scores on POES-S remained the same in intervention group before and during the COVID 19 lockdown, but in the control group the POES-S score was higher after the lockdown, than before. The findings diverge from surveys on wellbeing among participants with pre-existing mental health conditions, reporting poorer mental health and wellbeing, and increased levels of psychological distress during COVID 19 lockdowns, due to for instance isolation and loss of routines. (52,53) Accordingly, we cannot explain this development in POES-S, in the control group. A circumstance might be, that one may self-rate one´s own activity engagement higher when the restrictions are attributed to external conditions, and not to e.g., psychological or health related factors. However, this is only speculations, and more research is needed to better understand environmental and personal factors that impact change in activity engagement.

Methodological considerations

This study has several strengths. A sample size calculation was performed prior to recruitment. The trial reached the intended number of participants. Randomization was conducted with adequate allocation concealment. Blinding was obtained when possible. All outcomes are reported, and analysis is based on intention-to- treat analysis. MA&R was delivered with good and optimal fidelity, indicating that implementation of the program was satisfactory at all seven sites, taking part in the study. Attrition rate was rather low. 17,8 % of those allocated to MA&R, discontinued the intervention. The study also has limitations. It was not possible to blind participants and staff to intervention allocation, which increased the risk for expectation bias. (54) The outcome measures consisted of self-report instruments, more prone to bias then assessor-rated or objective measures. Since most outcomes concerned subjective experiences, we deemed that the measures applied, where appropriate to investigate the study`s hypothesis, and were clinically relevant. Outcomes were only measured twice, at baseline and post intervention follow up. MA&R is a complex intervention, with multiple interacting components, measuring only twice does not provide information about whether there were distinct modes or components that were more effective, for instance the high intensity mode in MA&R I vs. the low intensity mode in MA&R II. We cannot elucidate whether all components in MA&R are equally effective or ineffective. The trial was partly conducted during the COVID 19 pandemic, which likely impacted intervention delivery and outcomes. The results from the trial may be unique to this context, thus limiting the study`s external validity when generalizing the findings to a "normal context", not affected by lockdown and restrictions. We did not obtain data on the participants service use in respect to standard mental care. In this study, standard mental health was broad, and we do not have information about what participants received. The lack of information causes imprecision in the study, for instance unclarity about the comparator and the treatment-control contrast. (55,56)

Conclusion

The trial did not provide evidence for MA&R, a peer co-led occupational therapy intervention that being better in promoting activity engagement, personal recovery, functioning or quality of life, than the standard mental health care delivered in the CMCHs, ASSCs or rehabilitation teams. Over time, participants receiving MA&R and participants receiving standard mental health care significantly increased activity engagement, functioning and quality of life. Significant improvements in personal recovery, where only found among participants in MA&R.

The control condition in this study, services as usual, may have explained why MA&R was not superior to standard mental health care, since some of the core components in MA&R also were available in the services that we compared MA&R to. The differences between the RCT arms may have been smaller than anticipated. The components that made MA&R unique, compared to standard mental health care, namely the individual support to engage in activities outside the interventional setting, were partly hampered during and after the COVID-19 lockdown. The study showed that an intervention combining multiple modes, group sessions with individual sessions, and one-on one support, is feasible and acceptable for people with psychiatric disabilities. Post hoc analysis revealed a surprising finding in respect to levels of activity engagement before and after the pandemic. We cannot recommend MA&R to be implemented into mental health practice. The attendance rates, relatively low attrition rates and tendency towards a between group differences before COVID 19, justify that the intervention should be evaluated again under "normal conditions". We recommend that MA&R is revisited in respect to refinement of program theory and anticipated change mechanisms. We suggest that future research focus on establishing determinants for activity engagements and incorporating this knowledge into MA&R, before evaluating the program for its effectiveness in a RCT.

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Disclosure statement
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Author contributions
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Data availability
Data is not publicly available. Data obtained in the study, can only be used for the performance of the study, according to the permission granted from the Danish Data protection Agency. If access to data sets is required, an application must be handled to the institutional agency for data protection "Videncenter for Datasikkerhed" (replaced the Danish Data Protection Agency in the project period).

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Research Article

"Moving on to an Open World": A Study of Participants' Experience in Meaningful Activities and Recovery (MA&R)

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Background. Meaningful activities and Recovery (MA&R) is a peer coled occupational therapy intervention, to support occupational engagement among persons with psychiatric disabilities. *Aim*. To investigate participants' perspectives on how MA&R influenced occupational engagement and recovery processes. *Material and Methods*. A qualitative study with a phenomenological-hermeneutic design. Individual semistructured interviews were conducted with three women and ten men who had participated in MA&R. Participants were recruited from community mental health centres and municipality mental health services in two Danish municipalities. Analysis strategy was based on Malterud's Systematic Text Condensation. *Results*. MA&R was perceived as a practical approach to recovery, by providing an opportunity for reorientation, meaning, making in mundane activities, and a new outlook on everyday life. Participating in MA&R challenged a black and white approach to activities, put emphasis on "the little things", and enhanced curiosity, presence, and joy in occupational engagement. *Conclusion*. MA&R supported participants in developing a new "lens" on meaningful activities. The lens enhanced occupational engagement and made it possible to live according to personal preference. Results can inform further development and delivery of recovery-oriented occupational therapy interventions and add to the understandings of how occupational engagement and recovery are intertwined and manifested through everyday experiences. Thus, occupational engagement is an important target for recovery-oriented interventions. Occupational therapists and peer-workers coleading such interventions is feasible and makes good sense to the participants.

1. Introduction

Mental disorders are one of today's largest public health challenges, estimated to affect 38 percent of the EU population each year [1, 2]. Mental illnesses impact peoples' functioning and quality of life [3–7], as well as their abilities and opportunities for occupational engagement [8–10]. Research has found that what people do, such as time spent in a variety of activities and how they feel about what they do in terms of valued and satisfied activities, are important for health and well-being [9, 11–14]. Occupational engagement has been described by Black et al. [15] as; the active involvement in occupation, finding value and meaning, balanced engagement, subjective experience of engagement, developing identity through occupation, and social and environmental interactions. Occupational engagement plays a significant part in the recovery process [16–18]. Personal recovery is a unique and personal experience that encompasses hope, identity, meaning, and personal responsibility [19–21]. Regardless of the presence of mental illness, recovery is an ongoing process and a journey of finding ways to a meaningful life and developing valued social roles in the community, working towards better mental health [22–24]. Five key components for personal recovery process' have been identified under the acronym CHIME Connectedness, Hope and optimism, Identity, Meaning and purpose in life, and Empowerment [20].

Research investigating the links between recovery and occupational engagement has found that recovery is experienced through engagement in ordinary everyday activities in line with the "normal" roles and responsibilities, hereby rebuilding hope and connecting to an ordinary life in the community. [16, 17, 25–28]. Although a link between occupational engagement, well-being, and recovery has been established, there are only few evidence-based interventions targeting engagement in activities. More knowledge is therefore needed on how engagement in meaningful activities can be supported as a crucial part of the recovery process [29–31]. To address this, manualized programs [32–34] have been developed and investigated, to inform occupational therapists in mental health and how they can help patients support occupational engagement. Among the programs are Balancing Everyday Life (BEL) [32, 35–37], Action Over Inertia (AOI) [33, 38, 39], and the Occupation Matters Programme (OMP) [34] Occupation Matters and Balancing Everyday Life (BEL) are explicitly informed by previous lifestyle interventions such as the Lifestyle Redesign approach whereas the Action Over Inertia (AOI) manually describes its conceptual foundations as rooted in CMOP-E, recovery, Do-Live-Well, and capabilities frameworks. [14, 32–34] The programs provide knowledge on, and stimulate to reflections about occupations in relation to health, wellbeing, and recovery [32–34]. BEL and AOI both revolve around reengagement in healthy, satisfying, and varied occupational patterns (occupational balance) [32, 33], while OPM focuses on reengaging in occupations and redesigning lifestyle that facilitate recovery [34]. The interventions are led by occupational therapists, have a group-based format (AOI can also be delivered as a one-on-one intervention), and utilize various strategies such as home assignments and peer-support among group participants to facilitate change processes in relation to occupational patterns and occupational engagement [32, 34, 35, 37, 38]. Qualitative studies with participants with mental illness have found that reengaging in occupations during recovery often is a hard and demanding process [38, 40, 41]. It has been suggested that advancing occupational therapy interventions by offering individual support and incorporating collaborations between occupational therapists and peer-workers, may hold unrealized potentials for supporting occupational engagement and recovery [38, 40, 42]. Peer-workers are people with personal experiences with mental health problems, employed in mental health services to explicitly use their experiences to support others in their recovery [43].

Meaningful Activities and Recovery (MA&R) is a novel curriculum-based program to facilitate occupational engagement among persons with psychiatric disabilities [44]. MA&R differs from the earlier-described interventions, by (i) combining group sessions with one-on-one meetings (taking place interchangeably), (ii) being coled by a peer-worker and an occupational therapist, (iii) offering participants individual support to explore, engage, and practice occupational engagement in their homes or community, and (iv) have a longer duration in time. MA&R lasts for approximately eight months, whereas BEL, OMP, and AOI last between two to five months [44]. MA&R was investigated in a randomized controlled trial (RCT) for its effectiveness. However, the RCT design does not allow gaining insights into how MA&R was perceived by the participants, or how they experienced changes in occupational engagement and recovery during the intervention. The rationale for conducting this study was therefore, to provide a better and more nuanced understanding of the change processes in relation to occupational engagement and recovery during MA&R [45–47]. Thus, the objective of this study was to investigate the participants' experiences of the potential impact the MA&R had on their occupational engagement and to explore how the intervention's focus on occupations supported the participants' recovery process.

2. Material and Methods

2.1. Study Design. A qualitative study with a phenomenological-hermeneutic design [48–50] was chosen, to explore whether and how occupational engagement was affected through participation in MA&R, and if the occupation focused approach in MA&R, supported the participants' process of recovery. The phenomenological hermeneutic approach is a research method to elucidate and interpret peoples' meaning of their life worlds, situated in time and in everyday life. Guided by the theory of interpretation of Ricoeur, [51] a phenomenological-hermeneutic interpretation evolves over three steps: firstly, naive reading, structural analysis, and comprehensive understanding [48]. This study's point of departure was the understanding of the lived experiences of occupational engagement and personal recovery in relation to MA&R, as the phenomena was described by the participants. The study was conducted from December 2020 until May 2021, following the RCT intervention.

2.2. The MA&R Intervention. MA&R is based on principles from the Lifestyle Redesign ® program [52] and was developed into its current format in a collaboration between researchers, occupational therapists, and peer-workers employed in community mental health centres. The duration is approximately eight months and consists of 11 group-sessions and 11 one-on-one sessions led by an occupational therapist and a peer-worker (MA&R mentors). At group sessions, participants are introduced to topics related to meaningful activities and recovery, such as flow theory

[53], storytelling, and strategies for occupational engagement, e.g. goalsetting. The MA&R mentors facilitate the sessions together, present themes, draw on examples from everyday life, and facilitate group exchange. The one-on-one sessions are held in conjunction with each group session and serve as a forum for further reflection on themes presented at the group sessions, to catch up with missing sessions, or to prepare for the following session. A detailed description of the MA&R is presented in the protocol paper by Bjørkedal et al. [44].

2.3. Participants and Settings. Thirteen participants were recruited from a larger sample of individuals with psychiatric disabilities, included in the MA&R RCT. MA&R was evaluated in a multicentre trial, with community mental health centres (CMCHs), a rehabilitation team, and activity and social support centres (ASSCs) as participating sites. The CMCHs delivered multidisciplinary treatment according to the Flexible-Assertive Community Treatment model, while the rehabilitation team delivered various rehabilitation services, mainly group based, such as self-esteem groups. The ASSCs were drop-in services, which means that they did not require referral or visitation. The ASSCs offered a wide range of activities, e.g., social happenings, open cafes, and creative activities. Participants in this study were affiliated to one of the sites when they enrolled in the MA&R trial.

The sampling strategy was based on maximal variation sampling regarding sites, sex, age, and time since completing the intervention, for variations in experiences to be explored [54, 55]. Participant selection criteria included men and women in various ages, recruited from the different sites (the rehabilitation team, ASSCs, and CMCHs) and those who had participated in MA&R in various timepoints before the interviews. We also aimed to include participants who had both completed and discontinued MA&R, but unfortunately, participants who have decided to discontinue MA&R either refused or did not respond to interview invitations. Sample size was deemed sufficient according to Malterud et al. That meant criteria for information power: study aim, sample specificity, use of established theory, quality of dialogue, and analysis strategy [56]. We found that our study aim was not broad, nor specific, but somewhat in between, as it encompassed occupational engagement and recovery (broad) in relation to the MA&R intervention (specific). The sample size was somewhat specific, as it entailed people with psychiatric disabilities who had been participating in MA&R. However, they were also a heterogenic group in terms of age, sex, life circumstances, type of psychiatric diagnosis, and recovery process. As the interviewer was an occupational therapist with work experiences within the population group, we expected the quality of dialogue to be adequate. The analysis strategy was informed by thematic analysis, search for cross-cases themes and nuances; hence, more participants are needed to be included than if we had deployed in-depth analysis. Based on these criteria we deemed that sample size should aim for about 12 to15 participants.

2.4. Data Collection. An interview guide was developed addressing the research question. Extracts from the interview guide are presented in Table 1. Semistructured interviews were conducted with a phenomenological approach using a narrative method to gain insights into the participants' experiences with MA&R, occupational engagement, and personal recovery. The interviews were conducted from December 2020 until February 2021. They were recorded digitally and transcribed verbatim and anonymized [49, 57]. Due to COVID19, personal interviews were limited, thus, nine of the interviews were conducted via videocall or cell phone, format was chosen by the informant and ranged from 45-75 minutes with a mean time of 62 minutes.

2.5. Analysis. The analysis strategy was guided by Malterud's Systematic text condensation (STC) [49, 58], a descriptive and explorative method inspired by phenomenology. The method involved the following steps: [1] reading all materials and obtaining an overall impression and bracketing previous preconceptions; then, reread with focus on the study aim; [2] identifying and sorting meaning units, representing different aspects of participants' experiences from their participation in MA&R, and coding; [3] condensing the contents and meanings of each of the coded groups; and [4] synthesizing the contents of each code group to generalize descriptions and concepts concerning engagement in activities and recovery. Table 2 illustrates the analysis process. First and last author read the interview transcripts, discussed preliminary themes based on the overall impressions, identified and sorted meaning units, and developed codes. Contents and meaning where condensed and discussed, and finally synthesized by first, second, and last author.

2.6. Ethical Considerations. The study was conducted in conjunction to the MA&R RCT approved by the Danish Ethic Committee (H-18017307), and the Danish Data Protection Agency (VD-2018-299, I-Suite nr: 6543). It followed the principles from the Helsinki declaration [59]. Informants were informed about the study and its purpose and written informed consents were obtained. All references to individuals and quotations have been anonymized.

3. Results

3.1. Participants. Ten men and three women participated: age 25 to 50 years old. Four participants were students, the others were either job searching or received early retirement pension. The participants had various psychiatric diagnosis, about half had schizophrenia spectrum disorders. Participants had all completed MA&R, 0, 4, or 12 months prior to the interview (Table 3).

3.2. Findings. A hierarchical structure of themes was constructed during the inductive steps of analysis, revealing one overarching theme, capturing participants` overall perceptions of MA&R: *A practical approach to recovery*, along with three subthemes, each describing change processes in relation to occupational engagement and recovery (Figure 1).

3.2.1. A Practical Approach to Recovery. MA&R was perceived as a pragmatic course, due to its future orientation towards activities and its nondiagnosis related curricula.

Table 1: Extract from interview guide.

Research question	Examples of questions posed in the interview
Whether and how MA&R enabled activity engagement is seen from the participants perspectives	How would you describe MA&R to me, assuming I had never heard of it? If/how did the course affected your view or reflection upon activities in your daily life? Have you explored new aspects of your daily life since entering the course?
Whether and how the intervention's embedded focus on activities supported the participants' recovery process	Has the course provided you with activities? Has participation in the course enabled you to do more of what you want? Has participation in the course changed the way you think about quality of life?

Table 2: Illustration of the analysis process from meaning unit to theme.

Citation number	Meaning unit	Condensed	Code group	Theme
194	"And were I saw no possibility for attaining any sort of recovery or getting any sort of meaningful activities into my daily life, I do have a positive view on this today, and that is partly because I dared to ask for help, because this entails a great deal of embarrassment to me. I find it embarrassing to ask for help for things that other people do not even think about, but just do. Or at least that is what I tell myself"	Taking initiative and asking for help to attain my apartment, made me look positive on recovery as a possibility for me. Daring to face the perceived embarrassment was a big step.	Abilities: Taking charge asked for help. Respite	I am not to solve myself as a problem.
195	"You know what, maybe it just has not sunken in yet, because that's right, taking the initiative to ask for help that is a big deal, that is a very big deal. So yes of course, something has happened within me and as I said, asking for this help, help with my apartment, is a result of this project"			

Table 3: Description of participants.

Participant number and gender	Age/ range	Diagnosis	Employment status	Time since MA&R
(1) Male	40-45	Schizophrenia	Early retirement	4 months
(2) Female	45-50	Attention deficit hyperactive disorder, borderline personality disorder, and PTSD	Early retirement	One year
(3) Male	25-30	Schizophrenia	Welfare	One year
(4) Female	30-35	Depression	Job training	2 months
(5) Male	50-55	Depression	Job	4 months
(6) Male	20-25	Obsessive compulsive disorder, generalized anxiety, and stress	Student	Finishing
(7) Male	50-55	Unknown	Early retirement	Finishing
(8) Male	25-30	Schizotypal personality disorder	Student and job seeking	4 months
(9) Male	35-40	Schizotypal personality disorder	Job seeking	One year
(10) Male	45-50	Obsessive compulsive disorder	Early retirement	Finishing
(11) Male	30-35	Schizophrenia	Student and job seeking	Finishing
(12) Male	30-35	Psychosis and stress	Student	Finishing
(13) Female	45-50	Depression	Early retirement	3 months

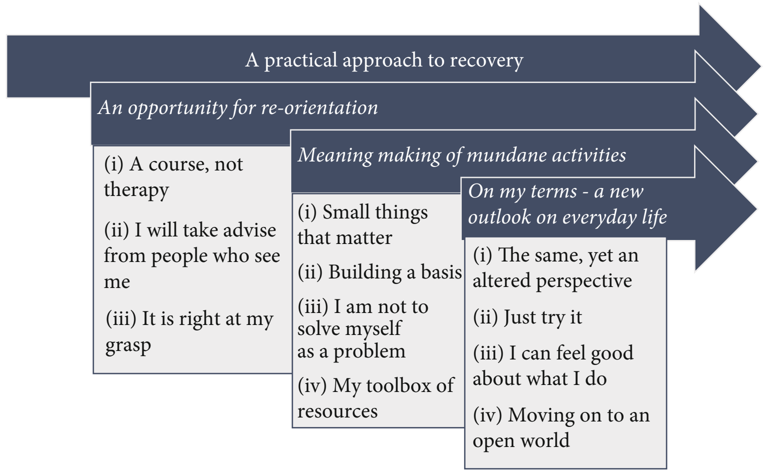

Figure 1: Overview of themes: Overarching theme, main themes, and subthemes.

Participants compared MA&R to having a personal trainer supporting engagement in activities. They valued the individual and flexible approach in MA&R and that they were free to engage in MA&R and in occupations, in their own pace, and according to their own offsets, for instance, not feeling that they should live up to explicit expectations about engaging in predefined activities. Participants highlighted this individually tailored approach as essential for their engagement. Some stated that they felt that there were major differences among them and the other persons participating in the group sessions. Not seeing common features or experiences among fellow group of participants impeded the participants feelings of connectedness and engagement during group sessions. Participants stated that the differences between them and other participants in the group, in respect to personal stages of recovery could be both a value and a hinder as those further along in these processes felt more alone.

"To me it was a little surreal, seeing that it was a recovery course, I expected it to be directed towards people who were a little more in the same state as me, where you have gone through the worst parts (illness red.) and is preparing to rebuild your everyday life—and there she (another participant) was in what seemed to be the worst crisis of her life—-and here, by talking with my MA&R mentor, he enabled me to use less energy on other participants situation (…) where, in other group-settings I have become an "assistant-teacher" (…) and thus forgetting my own needs" (participant 4).

Here, the peer-worker enabled participants to draw parallels from the themes in MA&R and everyday life. Further, the peer-worker brought authenticity by still being in the recovery-process, introducing recovery as a possibility. Overall, participants perceived their engagement enhanced as they felt met with respect and equality from the MA&R mentors.

3.3. An Opportunity for Reorientation

3.3.1. A Course, Not a Therapy. The fact that MA&R was a course and not a therapy was important to several of the participants before entering the course. It was valued that MA&R was not centred around illness or psychoeducation. Participants felt enabled to contemplate upon bettering their personal circumstances and valued the opportunity for personal exploration and perceptivity of everyday life.

"It was just what I could use, somebody who brings something positive and some ideas and suggestions, as to how I can better my life, without digging in what went wrong. And that is why I said "yes, please", also because it was a course, not a therapy!" (participant 2).

Having the curricula in focus provided participants with a relaxed and informal climate during group sessions, where illnesses became less prominent. The focus on activities and recovery initiated a process of altering perspective. From going through the day on autopilot to identifying which activities they wanted to engage in, and thus discovering that they already had several meaningful activities in practice.

3.3.2. I Will Take Advice from People Who See me. It was important for the individuals to feel recognized for their personality by MA&R mentors to perceive their encouragement as sincere. Hence engagement was fostered during the course when advice given was trusted e.g., MA&R mentors having a humble approach without dictating tasks. This inspired participants to engage enthusiastically throughout the course.

"One of the greatest things was their ability to see me. When the course ended, we all got a little postcard on how they perceived us and it was like they pointed out some things that weren't noticeable for me, and that was quite moving it made me feel very comfortable and there was a warmth to it, and it was not a clinical experience (…) but safe" (participant 9).

Feeling seen by the MA&R mentors, strengthened a sense of positive obligations in participants. Moreover, having the MA&R mentors to share their commitments with, promoted engagement in MA&R and a collaborative process around engaging in activities.

"It made me not give up, because hell, I wanted to be able to say that I did something, you know, when she (the OT) suggested something, then I had to try it out or try to look into it (..) it kept me on my feet, I had to do it before we saw each other again, whereas if it wasn't for the course, I would have been like "oh yeah, I will do it another day" and then it wouldn't amount to anything" (participant 13).

Conversely, not all participants did perceive MA&R as engaging. Some participants had entered MA&R with expectations of getting practical help or better managing everyday activities, so they became less arduous. They expressed disappointments by the end of the course, as they felt that these expectations were not met by the MA&R mentors, or they did not experience improvements in relation to performing everyday activities more effortless.

3.3.3. It Is Right at my Grasp. It was commonly expressed that throughout MA&R, participants became aware that the term "activity" could be understood in several ways, in the sense that activities are individually defined as meaningful. Flow-theory and the discovery of absorption in seemingly mundane activities were highlighted by many as a concrete tool, easily available, and gradually adopted into ordinary day-to-day activities.

"It has definitely broadened my understanding of it (recovery), in the sense, that to me it is a rather uplifting thought, that it isn't just appointments with a psychologist or medication, that can stabilize me (…) but that these more concrete things, these small buttons, seemingly obvious buttons close to you, can mean that your symptoms can be dismantled" (participant 4).

Hereby, participants felt disburdened, enabling them to lower their expectations towards feelings of accomplishment now becoming more in line with their capabilities. It nurtured a curiosity of exploring meaning and pleasure in well-known everyday activities. The participants stated that it helped in applying a new perspective on daily activities available right at their grasp. However, one participant could not lower his expectations of authoring a book, for instance, by starting a process of write and rewrite, not aiming for the text to be perfect at first try, and felt inert, passive and not able to succeed during the course.

3.4. Meaning Making in Mundane Activities

3.4.1. Small Things That Matter. Several participants stated that the "little things", mundane, often taken-for-granted activities, were not irrelevant, just because they were "little". They felt inspired by the idea of "size" of activities, "It's not either skydiving or sleeping, but it can be somewhere in between" (participant 7). Knowing that they need not do "grand" things, to make up a day of achievement, meant a greater appreciation towards ordinary elements in their everyday life. Several participants described that a new perspective led to further engagement in available tasks e.g., making plans to go shopping and engaging in self-care beforehand, now made grocery shopping a meaningful activity, or simply smiling or saying hello to a stranger there, meant having had an interaction that day.

"Just such a thing as watering the plant you haven't nurtured, after having starred at it for three weeks, hell, that quality of life. So, this has also changed. Definitely. In the sense that these smaller things they have a catalysing effect on many other things, like quality of life. And this is where I find meaning, in the small, close to home things" (participant 1).

Realizing that meaningful activities encompassed multiple types of activities that were deeply personal in terms of how they were performed and what meaning they had to people was highly valued among the participants. Identifying everyday activities that were meaningful, fostered self-determination in the participants, and helped them to avoid comparing themselves to others. Participants stated that this notion, made the meaningfulness more evident in the activities they were occupied with. It also enhanced their motivation to try out small activities, and their realization that not all practical tasks had to be chores but could also be enjoyable. Importantly, it was primarily these close to home activities that were possible. Social activities, such as seeking a tutor to initiate writing a book, or (re)establishing social relationships, were, for many participants, hindered by Covid-19 restrictions.

3.4.2. Building a Basis. Some participants described that MA&R had altered their perceptions of their living situation, acknowledging its potential in rebuilding a steady fundament for wellbeing in everyday life. No longer a place to hide, the home became a safe environment and a catalyser for further activities. One participant who had a sleeping disorder as comorbidity, made her bedroom a sound space, since much of her time was spent there: adding flowers, making the bed, and airing out. Another participant let his spiritual beliefs stand out in his home, making it his sanctuary. Hence, meaningful engagement could be grounded in something as fundamental as watering ones plants.

"These meaningful activities are very close to home and daily life (….). It relates to taking care of myself, taking care of my home, and making this work, getting the basis to function" (participant 1).

One participant, however, did not feel satisfied as his wishes of wanting help to move and start over in a new place, could not be met by the MA&R mentors.

3.4.3. I Am Not to Solve myself as a Problem. By focusing on existing resources, participants enhanced their awareness towards activities they already did, instead of focusing on the things they did not.

"…And realizing that everything doesn't have to be perfect according to other people's standards, but that you set your own standard, and the apartment does not have to be shiny and perfect. This is what I can do, this is my level, then other people can do what they are good at" (Participant 9).

Several participants described being more realistic about, and no longer ashamed of their capabilities. This led to a change of approach from neither-nor to "I can do both", with limits. The acceptance fostered new insights, where disabilities were not a failure, but just a part of being that person at that time. This softened up a black and white perspective, where either you do the activity, or you do not. Participants experienced how formerly good activities felt detrimental when too much was initiated at once. This led to a focus upon what they could in fact do, creating more balance towards initiating activities in line with personal levels and meanings. Importantly, was to overcome the embarrassment that activities mundane to others, e.g., getting out of bed and on with the day, could be a struggle. Leading one participant with the courage to ask for help with his apartment, so that he could focus his energy upon engaging in other activities.

3.4.4. My Toolbox of Resources. Throughout MA&R, participants felt supported in identifying their resources and utilizing these when engaging in activities, and conversely exploring how activities could be used as resources. Participants found it easier to engage in activities for their personal benefits, when they were curious about those in which they could fully immerse themselves. Participants reported that awareness and understanding of one's possibilities for wellbeing, when engaging in activity, came from realizing that focus was not devoted to symptoms if they were actively participating in activities. This gave rise to taking charge e.g., going to the park outside when sensing anxiety, or simply just placing yourself on the couch with a pet, just do something different. By noticing when activities felt good, opportunities arose to enforce these, and opposite, to distance from activities which felt draining.

Accessible activities became part of a personal toolbox. Walking became a proactive strategy for one participant when he felt apathic. Another started to take breaks to lean back and be attentive of own needs when his OCD took charge. Some participants focused on the feelings accompanied with an activity, such as tidying up could foster engagement and be enjoyable. Others adopted the notion that it is okay to slobber, when cleaning and not do 100%, which motivated to engage in activities.

"I have given myself permission to slobber, I like this principle of slobbering, at least now, so when I am cleaning, I do not have to get into every corner, but superficial cleaning is also a thing. Where before (…) when having to be this extreme, resulted in me not being able to handle anything at all" (participant 9).

3.5. On my Terms—A New Outlook on Everyday Life

3.5.1. The Same, Yet an Altered Perspective. When asked about daily patterns and routines, most participants deemed that their everyday life looked the same as before MA&R, with few alterations. However, contemplation upon known routines and activities, stirred several participants away from "autopilot", meaning that everyday life did not feel the same, due to an altered perspective of self-determination upon what makes up an activity.

"Tomorrow, we are going to the laundromat, and I am looking forward to it. The walk down there, and sometimes we sit and wait for the laundry to finish. And where this earlier was associated with a lot of anxiety, it has now become much better, to be able now to tell yourself "I'm just going to sit here". But actually, being able to sit there, it gives me so much joy and all I want to do is improve this, what I have, more than I want to add anything, that's how I feel (Participant 9) ".

Those participants who adopted new perspectives particularly did this in relation to "smaller" everyday activities, and by increasing their awareness of the opportunities these arose. For instance, one participant explained that bringing his camera, when taking a walk in the park, introduced new possibilities of experiencing a sense of flow when capturing nice motives. For some participants, routines were changed with emphasis upon favouring own needs and wants, e.g., one participant now started to make coffee as a morning routine:

"During my sick leave and while I was in MA&R, I practiced making myself a good cup of coffee every morning on my slow brewer, because making coffee or tea for myself was something I had never done, only if there were others" (Participant 4).

Reflecting on how activities could be a barometer for the recovery process, this participant reduced her working hours to resume good routines.

3.5.2. Just Try It. MA&R created a space for trial and error where participants could experience success both inside and outside the group. Learning that engaging in activities took practice and not worrying about a "perfect outcome" was motivational and made it easier to initiate activities and feel more ease and presence in them.

"I would rather just try it out, and maybe it's not fun for me, or maybe I'm not good at it, but it might become enjoyable, or you could get better at it (…) but then you know your limits in that period and this might change as well" (participant 8).

One participant challenged his all-or-nothing approach, (job or no-job), and asked for job-training at the job centre, leading to developed job-abilities, slowly easing his way back to work-life routines.

This contributed to a different approach to activities, as opportunities for creating momentums.

"I think there is a positive spill over effect, if something is enjoyable, then it becomes easier to do other things too" (Participant 11).

3.5.3. I Can Feel Good about What I Do. Some participants expressed being able to, to some degree, manage their own wellbeing through activities. Participants highlighted that learning about flow-theory and being able to identify with a state of flow, was a positive experience. Knowing that flow could appear in their natural environment merely by putting on music or folding laundry, made participants aware that this was attainable for them and that they could feel "normal".

"I have become aware of it (flow red.), and I think that is the important part. I have become aware that I, for brief periods can feel like everybody else and be occupied by something and go into that state. That process is what has become clear to me" (Participant 1).

Initially, it required a lot of awareness to engage, but over time "just" engaging in activities became more intuitive e.g., by taking your camera with you on a walk. By focusing on "the good" in activities and letting achievements outweigh defeats, several participants were enabled to see possibilities in their surroundings, where the "to-do" list was replaced with a "try-this" list. When a participant in the interview was asked if she was better able to do what she wanted to do, she answered:

"Yes, I feel that I am, that I do. There is always that thought when you deal with recurring mental illness "it will come back", you know? Right now, I am on a positive road, and hopefully, when it goes uphill again, then I will try and focus more on doing some of the things that I have discovered makes me happy and does me good, by taking me out of my head—having had this year to figure out what these things were" (Participant 13).

The participants felt more equipped to verbalize their concerns and avoid situations that could result in defeat. Several participants felt more able to express their needs towards friends and family.

3.5.4. Moving on to an Open World. Through engagement in activities and by enhancing the experiences of respite, participants felt their illness less prominent. This made recovery seem attainable by using activities as an indicator for mental wellbeing, e.g., the reattainment of bicycling or the awareness of skipping good morning routines.

"I remember how good it felt when I started riding my bicycle around town again, because I have always identified myself as one of those city-types who rides their bicycle around town. But all those years being ill I only took the bus, and I was in the back of the bus hiding, primarily riding the bus in knowing, that in this place I wouldn't run in to anybody I knew. (…), and it made a huge difference for me when I started bicycling again, because it was a recognition that, all right, now I am aware that I can possibly run into someone, so in doing this I felt like I moved on to an open world again" (Participant 4).

Choosing daily activities more in tune with own preferences such as their ability of feeling absorbed or respite or simply perceiving taking a break as an activity, nurtured hope, and experience of living meaningful lives. Several participants also spoke of the possibility of becoming peer-workers themselves.

4. Discussion

The findings in this study illuminate whether and how MA&R supported activity engagement and subsequently, the recovery process from the participants' perspectives. The program's emphasis on reorientation in daily life, for instance in relation to meaning making of occupational experiences, and rethinking interests, values, aspirations, and identities, the personal orientation, and its pragmatic approach with emphasis on trial and error was highlighted by the participants. The activity-oriented focus, together with a respectful tone, supported participants to engage and experience meaning in activities within their reach during MA&R. Participants adopted several considerations for mundane activities learning that these could provide joy and immersion, and their homes and surrounding became pivotal for wellbeing and a safe space to recoup.

4.1. Occupational Engagement and Recovery. Our findings align with results from Sommer et al.'s metasynthesis on recovery [60], identifying three key processes: being, doing, and accessing. Contextualized by the constraints psychiatric disabilities encompass, these processes' make everyday life experiences into opportunities for accessing resources, enjoyments, and new possibilities intertwined with opportunities for recovery. In their metasynthesis [60] being and doing are described as generic recovery processes. *Being* refers to the temporal unfolding of meaning, being well in everyday life, belonging, and accepting. *Doing* refers to participating and contributing through everyday activities within a social context where the person feels valued. In our study, participants distinguished between daily life looking the same, and feeling the same. We interpret this as recovery through the descriptions from MA&R participants, possibly being closely linked to temporality and occupational engagement, more than to occupational performance. This poses a question whether MA&R first and foremost support recovery in terms of wellbeing and experiences of meaning, and how this can be achieved with or without making actual changes in daily activities, but by changing perspective. Contemplating on the findings, that the smaller day-to-day activities took presence could be a result of the Covid19 pandemic, having affected *accessing*—the third process by Sommer et al., when restrictions and lockdowns closing opportunities to attend activities in the greater social surroundings. Thus, restrictions could have had serious consequences on quality of life [61–64]. But, having had an altered perspective on daily routines and quality of life, participants perhaps saw possibilities ahead and felt that everyday life was more in tune with wishes, which depicts having more attention towards building a solid basis where one could feel good. By change of perspective, making changes in day-to-day activities, otherwise not clear, become noticeable.

Present results also have ties to findings from a scoping review by Doroud et al. [16], examining recovery seen through occupational engagement, discovering a process set in three interrelated stages with impact on personal recovery (CHIME) [20]. Standing out in the current study are especially the first two processes: (i) recovery as gradual occupational reengagement—doing to get started and (ii) recovery as engaging within the stream of everyday occupational life. The latter, (iii) recovery as full community participation and citizenship, was partly disrupted by the pandemic.

Activities on hand and their tangibility through trials rendered as a solid basis, and a prominent theme appeared through the interviews, that daily life did not feel the same by applying a new focus of temporality whilst being in activity. By working with "trial and error" in activities in- and outside MA&R, engaging in these became less fearful through the perception of it as practice for the "real world". This is in line with Doroud et al. [16], who found that small tasks can help a person rediscover hope and constructively reappraise their capabilities and resources. Several participants expressed that accepting one's own capabilities was difficult but was aided in the individual meetings with

MA&R mentors, helping decrease demands towards oneself, accommodating them to set their own standard for meaningful activities. Hereby, in line with other research from Black and colleagues [15], *a subjective experience of engagement* became clear, with examples such as riding the bicycle across town again, being mindful about the bedroom or the different aspects of going to the laundromat, and just *be* with a friend.

Although there often might be overlaps between activities that are culturally and personally valued (e.g. work is a social expectation in most cultures, and at the same time personally significant to people) [65, 66], findings in this study suggest that meaning making in activities are, when narrowed down, *in the eye of the beholder*. People have different ideas about what make meaning in their lives. Consequently, promoting occupational engagement is not a process that should be taken for granted by merely assuming what kind of occupational opportunities people with psychiatric disabilities need, for instance by building mental health services that solely offer predefined activities. Assisting a person to discover where feelings of absorption appear, and to strengthen the awareness of activities, mundane, familiar, or new, can foster a feeling of connectedness to everyday life. Enabling the person to build upon the personally defined occupational life, in line with Doroud et al. [16] can support *recovery through engagement in the stream of everyday life*.

Findings from this study stress the importance of meeting the person's recovery goals. Participants became disengaged when they did not feel met by the MA&R mentors. Persson et al. proposes in their analysis of value dimensions, meaning and complexity in occupations, that occupations have symbolic value on a personal and cultural level. Through choices of occupations, the individuals communicate aspects of themselves, to the immediate world. The social environment communicates "back", to the doer, providing feedback on whether the behaviour is acceptable and valuable according to cultural norms and ideologies. [67] Participants who felt met, seen, and/or supported in MA&R, began a process of putting less emphasis on the symbolic value in occupations from a cultural level. Participants described being less ashamed of not being able to perform activities taken for granted by broader society, such as getting up and on with the day. They also stated that MA&R helped them avoid comparing themselves to others. Instead, MA&R supported an exploration of the symbolic value in occupations on a personal level, acknowledging that lying on the couch with a pet, or taking photos in the park, where significant activities if they mattered to the participants. This shift of focus might for some participants have led to a greater self-acceptance and soften up a critical self-image of a person having disabilities. Towards putting more emphasis on the symbolic value in occupations on a personal level. This may have fostered gradual occupational reengagement [16] and initiating a positive cycle to experiment further in other activities, because of their potential of enjoyment, FLOW, or sense of accomplishment. It may also have aided participants to *develop identity through occupation* [15] in knowing their limits and gaining a stronger sense of self, which is needed to withstand the effects of negative expectations and stereotyping from the broader community [68].

Findings from this study point to both similarities and differences with qualitative studies on participants experiences with BEL [35–37], AOI [38], and OMP [34]. Perceiving MA&R as a practical take on recovery aligns with results from studies investigating participants experiences in relations to AOI and OMP. Findings from these studies showed that reflecting on the meaning in occupations and acknowledging the links between occupations, health, and wellbeing, facilitated feelings of hope and agency, and a sense of normality [34, 38]. Similar to participants from the OMP [34] study and the BEL study [36], participants in MA&R described developing confidence, which enabled them to dare to try out or reengage in activities that mattered to them. The programs resolving on the meaning and value of small, mundane activities seemed highly valued among participants, and indicate that providing people with psychiatric disabilities knowledge and opportunities to explore and engage in occupations might create new pathways to recovery by strengthening a positive identity, providing new sources of meaning, building connectedness, nurturing hope, and empowerment [34–36, 38]. One striking difference between the findings in MA&R, and the results from the BEL, OPM, and AOI study was that the participants did not perceive peer-support among group participants as a supportive element in the intervention. They found that perceived differences between themselves and the other participants in the group was a barrier for engagement. Instead, participants in MA&R highlighted the peer-workers' role, for showing them new opportunities for engagement, and for drawing parallels between the sessions and their everyday lives. Thus, having occupational therapist and a peer-worker codelivering sessions make good sense to the participants, and may strengthen the program's potential impacts. Coproductions between peer-workers and occupational therapists, when developing occupation focused program, should also be considered when developing and refining recovery-oriented interventions targeting occupational engagement. Also, the individual approach in MA&R, was highly valued, which indicate that adding one-on-one sessions to group-based interventions may be a useful tool for tailoring person-oriented services. Participants' notion of feeling seen by the MA&R mentors was more prominent in the MA&R study, than in BEL [35, 37], AOI [38], and OPM [34], which suggest that combining individual sessions and support with group sessions, might foster distinct change processes in relation to occupational engagement. However, this needs further explorations. Overall, the findings in this study suggest that MA&R can be a relevant recovery-oriented approach as it addresses occupational engagement, an important recovery goal for people with mental illness. The MA&R RCT was a multicentre trial, and the program was delivered in both municipality mental health services and in community mental health centres, which indicate that the MA&R format may fit into various mental health settings were occupational therapists and peer-workers are employed.

4.2. Methodological Considerations. A stepwise purposeful sampling [54] was chosen within this somewhat homogeneous group of participants, seeking variation within different timepoints since enrolment in MA&R. Albeit, we were not able to sufficiently recruit in relation to demographic criteria, as male participants dominated, thus addition of female participants would have been advantageous. Due to COVID19, personal interviews were limited, thus nine of the interviews were conducted via telephone or videocall, the remaining four participants emphasized face-to-face interviews, leading to variations of data collection. The first author carefully secured a safe space to express thoughts invariably, and quality was not deemed affected by this fact.

While phenomenological philosophy is not as explicitly stated in STC as in Giorgi's method [69] or Interpretative Phenomenological Analysis [70], STC still shares the foundations of life-world experiences as valid knowledge [58]. STC in the current study procedure was invoked as a committed phenomenological analysis, a strategy chosen to bring forth the essence of the phenomenon [49, 58, 71]. During all steps of the research process a commitment to reflexivity was held [49, 71–73]. Early in the process, preconceptions were identified and returned to during analysis to secure bracketing. This was done by first author, who kept a reflexive journal during the research process, and wrote memos after interviews, and by last author who wrote down assumptions about participants' experiences with MA&R, prior to initiating the study [73].

To enhance trustworthiness and improve credibility, authors were engaged in a constant dialogue to consolidate on each level in the analysis, thus supplementing and contesting each other's findings to strengthen the understanding of the phenomena [71, 74, 75]. STC also explicitly prescribes recontextualization as the final step of analysis, validating interpretations and findings against the initial complete transcripts. However, the authors conducting the analysis were all trained occupational therapists, which may increase the risk of blind angles while consolidating the themes and interpreting the findings [49].

5. Conclusion and Clinical Implications

Findings from this study show that MA&R was perceived as a practical approach to recovery and that the activity focus in MA&R supported this approach. Participants highlighted the experiences of recovery through the "small things" in life, often taken for granted. They appreciated MA&R for its positive and future-orientation and personalized approach alongside opportunities for trial and error. The findings provided understandings of how occupational engagement and recovery are intertwined and manifested through everyday experiences. Aiding in personal recovery was an altered perspective upon activities, challenging the "big" or "small" activities and applying own terms towards meaningfulness and presence in daily life. Moreover, the findings indicate that occupational engagement can be enhanced, with or without increased occupational performance.

The MA&R course-setup enabled participants motivation to take-in curricula and apply knowledge towards activities. Knowledge was empowering in giving participants tools right at their grasp. The results from our study suggest that MA&R supported the participants in developing a new "lens" on meaningful activities—highlighting the value of everyday experiences for recovery and wellbeing.

Data Availability

The datasets used and/or analysed during the current study are not available, due to Danish Law and GPDR.

Conflicts of Interest

The authors declare that there is no conflict of interest.

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APPENDIX II

Interview guides

Interviewguide til studie 2:

Formål: At opnå en større forståelse af patientens og beboerens oplevelse af hvordan IMR-programmet har betydning for deres forestilling om recovery, så som hvad har været nyttigt, motiverende, stimulerende såvel som, hvad er der blevet taget handling på grund af IMR-programmet.

Videnskabsteoretisk ståsted	Forskningsspørgsmål	Teoretiske temaer	Spørgsmål/Spørgeteknik	Link til den analytiske tilgang
Fra et **hermeneutisk fænomenlogisk** perspektiv, er levede erfaringer viden, som tilegnes ved hændelser og i samspil med andre. Tilegnelse af sådan en viden er en måde at opnå ureflekterede og før teoretisk indgang til sfæren af levede erfaringer. Levede erfaringer tilegnes udelukkende som noget der er erfaret igennem det levede liv. Fænomenlogi. Denne forskningstradition undersøger menneskers levede oplevelser. Fænomenlogisk forskning bidrager med indsigt i personens egen fortolkning, overbevisning, forståelse, hvor referencerammen er en særlig gruppe af persons oplevelser. Forskningstraditionen er bedst egnet til problemstillinger, som involverer personers forståelse af relationer.	Hvordan oplever patienten/beboeren IMR-programmet har betydning i forhold til deres personlige recovery? Hvordan oplever patienten/beboeren IMR-programmet har af betydning for at formulere og tage handling på personlig recovery mål? Hvilke forskelle er der imellem ved målopstilling i IMR-programmet og personlige handleplaner?	**IMR-programmet** Stress-sårbarhedsmodellen Trans-teoretiske model **Recovery** Recovery: Process Recovery: mål Flow **Værdier** Håb og optimisme Personlige mål **Position i egen recovery** Identitet og selvopfattelse Relationer	**Indledende spørgsmål** "Hvordan kom du til at høre om IMR-programmet?" "Hvad var dine forventninger til IMR-programmet?" Hvad motiverede dig til at deltage i programmet? "Fandt du noget i IMR-programmet, som ikke var nyttigt?" "Har der været situationer i programmet, som du gerne ville have været foruden?" "Var der noget i IMR-programmet, som hjalp dig?" "Hvad er din erfaring med opstille mål?"	Mening/Holdninger Værdier

Videnskabsteoretisk ståsted	**Forskningsspørgsmål**	**Teoretiske temaer**	**Spørgsmål/Spørgeteknik**	**Link til den analytiske tilgang**
Dette kvalitative studie har fokus på **personlig recovery** med svær psykisk sygdom. Recovery er et koncept, som er udviklet af brugerbevægelsen og er baseret på ideen om, at en person er i recovery så længe personen er i en aktiv indsat for at genopbygge et meningsfuldt liv. Personlig recovery er en dybt personlig, unik forandringsproces med hensyn til ens holdninger, værdier og mål, færdigheder og/eller roller. Det er en måde at leve et tilfredsstillende liv på præget af håb og aktiv medvirken selv med de begrænsninger, der er forårsaget af sygdom. Recovery indebærer udvikling af ny mening og nyt formål i ens liv.	Hvordan oplever patienten/beboeren IMR-programmet har betydning i forhold til deres personlige recovery? Hvordan oplever patienten/beboeren IMR-programmet har af betydning for at formulere og tage handling på personlig recovery mål? Hvilke forskelle er der imellem ved målopstilling i IMR-programmet og personlige handleplaner?	**IMR-programmet** Stress-sårbarhedsmodellen Trans-teoretiske model **Recovery** Recovery: Process Recovery: mål Flow **Værdier** Håb og optimisme Personlige mål **Position i egen recovery** Identitet og selvopfattelse Relationer	**”Jeg vil gerne tale med dig om du har ændret dig i forhold til din psykiske lidelse:”** ”Fortæl lidt om det…” ”Har du oplevet, at få det bedre i forhold til din psykiske lidelse? ”Hvornår oplevede du det: at få det bedre første gang?” ”Hvad med det modsatte, altså at få det dårligt” Har du oplevet at få det dårligt til trods for færre symptomer på psykisk sygdom? Hvad har det haft af betydning for dig? **”Har du set nye sider af dig selv ved at deltage i IMR?”** Fortæl lidt om det? ”Hvornår i forløbet blev du opmærksom på de nye sider af dig selv?	Recovery Vendepunkter Identitet og selvopfattelse

			”Hvilke ydre faktorer påvirkede dig?” ”Hvad skete der med dig?” ”Hvilken betydning havde det for dig at skulle opstille personlige mål?” Har kravet om målsætninger i IMR-programmet påvirket dig? **”Har din deltagelse i programmet ændre dit syn på dig selv?”** -”Ændret dit syn på dine omgivelser?” -”Ændret dit syn på din hverdag?” ”Har den ændret, det du vil med dit liv?”	Forandringsprocesser Manifestation af forandringsprocessen

Hjælpe spørgsmål til at få fortællingen frem:

Hvad gjorde du/hvad var dine ønsker til IMR?

Hvad gjorde IMR-underviseren for dig under forløbet?

Kunne du tænke dig at deltage i IMR-forløb igen, Hvorfor/hvorfor ikke?

Vil du anbefale IMR til andre?

Supplerende/ Uddybende spørgsmål:
Det lyder som om_______
Det lyder som det er forskelligt fra_________
jeg tænker, er der andet____
Hvordan fik du_______
Spørgsmål til at identificere områder som patienten eller beboeren ikke har talt om.
Så fik du genkendt______
Jeg tænker om der er andre dele af IMR-programmet som har været__________
Hvordan fik du___________
Hvordan oplever du din situation________
Fortæl mere om______
Hvordan fik du________
Det lyder som om_______
Det lyder som det er forskelligt fra_________
Har din deltagelse i IMR-programmet fået dig til at føle anderledes om dig selv?
jeg tænker, er der andet____
Hvordan fik du_______

Interview guide

- Hvordan kom du til at høre om Vendepunkter?
- Hvad motiverede dig til at melde dig til kurset?
- Hvilke forventninger havde du?

- Hvordan har det været for dig at deltage i Vendepunkter?
- Jeg kunne tænke mig, her som det første at høre din helt umiddelbare holdning om det at deltage i Vendepunkter,
  - Hvad det betød for dig
  - Kan du sige mere herom?
  - Kan du give et eksempel

- Hvad gjorde mest indtryk på dig?
- Har du haft nogle dårlige oplevelser med kurset?

- Kan du fortælle om en eller flere situationer hvor du oplevede at du kunne brugde noget fra kurset i din hverdag.
  - Hvad var det du kunne bruge?
  - På hvilken måde?
  - Hvad var det der gjorde at du lige præcis kunne bruge det?
  - Har du lært noget nyt undervejs i kurset?
  - Har du kunne bruge det i din hverdag eller undervejs i kurset?
  - Eksempel: Handleplaner, kommunikation, livsstil, meditationsøvelser osv.

- Har du oplevet at få det bedre efter at du har deltaget i Vendepunkter
  - På hvilken måde?
  - Har kurset spillet en rolle?

- Kender du til begrebet recovery?
  - Hvad betyder det for dig?

Interview guide

- Hvordan kom du til at høre om Lær at tackle angst og depression?
- Hvad motiverede dig til at melde dig til kurset?
- Hvilke forventninger havde du?

- Hvordan har det været for dig at deltage i Lær at tackle angst og depression?
- Jeg kunne tænke mig, her som det første at høre din helt umiddelbare holdning om det at deltage i Lær at tackle angst og depression,
    - Hvad det betød for dig
    - Kan du sige mere herom?
    - Kan du give et eksempel

- Hvad gjorde mest indtryk på dig?
- Har du haft nogle dårlige oplevelser med kurset?

- Kan du fortælle om en eller flere situationer hvor du oplevede at du kunne brugde noget fra kurset i din hverdag.

    - Hvad var det du kunne bruge?
    - På hvilken måde?
    - Hvad var det der gjorde at du lige præcis kunne bruge det?
    - Har du lært noget nyt undervejs i kurset?
    - Har du kunne bruge det i din hverdag eller efter at kurset er stoppet?
    - Eksempel: Handleplaner, kommunikation, livsstil, meditationsøvelser osv.

- Har du oplevet at få det bedre efter at du har deltaget i Lær at tackle angst og depression?
    - På hvilken måde?
    - Har kurset spillet en rolle?

- Kender du til begrebet recovery?
    - Hvad betyder det for dig?

Interview guide IPS

Indledende spørgsmål:

"Hvordan kom du til at høre om IPS-programmet?"

"Hvorfor meldte du dig til IPS?"

"Havde du forventninger til IPS?"

"Jeg kunne tænke mig, her som det første, at høre din helt umiddelbare holdning om det at deltage i IPS?"

- Hvad betød det for dig?
- Kan du sige mere herom
- Kan du give et eksempel

"Hvad har gjort mest indtryk på dig?"

"Har du haft dårlige oplevelser med IPS?"

"Var der noget i IPS-programmet, som du ikke kunne bruge?"

Recovery og IPS:

"Hvordan var det, at have en IPS-konsulent?"

"Hvordan var dit forhold til din IPS-konsulent?"

"Hjalp din IPS-konsulent dig?"

-Kan du fortælle om en situation, hvor du følte at din IPS-konsulent hjalp dig?
- Betød?
- sige mere?
- eksempel?

"Det er jo noget helt nyt, at jobcenteret, som IPS jo er en del af, flytter ind i psykiatrien. Hvordan påvirkede det dig?"

- Betød?
- sige mere?
- eksempel?

"Vidste du, hvad du ville mht job/uddannelse?"

"Hvordan kom du frem til det?"

"Hvordan gik det med at komme i job/uddannelse?"

"Påvirkede det dig, at det gik så hurtigt/langsomt?"

"Hvordan var det at komme ud på arbejdsmarkedet/uddannelsessystemet?"

"Hvordan gik det på arbejdspladsen/uddannelsesstedet?"

"Valgte du at fortælle om din psykiske lidelse til din arbejdsgiver/kolleger/medstuderende?"

”Hvordan var det?”

”Hvordan blev du støttet af din IPS-konsulent efter du kom i arbejde/uddannelse?”
- Betød?
- sige mere?
- eksempel?

”Hvad var positivt ved at komme i arbejde/uddannelse?”
- Betød?
- sige mere?
- eksempel?

”Hvad var negativt ved at komme i arbejde/uddannelse?”
- Betød?
- sige mere?
- eksempel?

Recovery:

”Har du oplevet, at få det bedre i forhold til din psykiske lidelse?

”Hvad har gjort at du har fået det psykisk bedre?”

”Hvordan fik du det bedre?”
- sige mere?
- eksempel?

”Har IPS spillet en rolle?
- sige mere?
- eksempel?

Er der andre områder, hvor du har fået det psykisk bedre? Socialt, overkomme mere, leve på en anden måde?

”Har IPS spillet en rolle for de områder?”

”Har du oplevet at få det dårligere psykisk?”

”Hvad skyldtes det?”

- Betydning?
- sige mere?
- eksempel?

”Har IPS spillet en rolle?

”Har du oplevet at få det dårligt, til trods for færre symptomer på psykisk sygdom?”

”Hvorfor tror du det?”

Forandring:

” Har det gjort noget ved dig at deltage i IPS ?”

-Har det ændret dig?
-Hvordan
-Sige mere

”Hvad skete der med dig?”
(Socialt, personligt, din måde at tænke på)

”Hvad skyldtes det?” (arbejde, uddannelse, IPS-konsulenten ect)

”Er du den samme person i dag, som du var for år tilbage?”

- ”Hvad er der sket med dig?”
  ”Hvad skyldes det?”
  ”Hvornår skete det?”

”Er dit syn på dig selv det samme nu, som det var år tilbage?”

”Er din hverdag den samme nu, som for år tilbage?”

”Er dit syn på fremtiden det samme nu, som for år tilbage?

APPENDIX III

Statistical Analysis Plan

Statistical analysis plan (SAP) for Project Meaningful Activities and Recovery (MA&R)

NCT 03963245

JULY 26TH, 2021

Content

1. General information

1.1 Title of the project

Project Meaningful Activities and Recovery (MA&R)

1.2 Trial registration number

ClinicalTrials.gov NCT03963245.

1.3 SAP version number

This is a detailed version of the SAP description in the protocol (Danish latest version 5 sent to Regional Ethics Committee e) and protocol paper (Bjørkedal *et al.*, 2020). This detailed SAP is version 1, July 2021. The headings in this SAP are in many instances aligned with the structure recommended by Gamble et al. (Gamble *et al.*, 2017).

1.4 Names, affiliations, and roles of SAP contributors

This SAP has been drafted by Siv Therese Bogevik Bjørkedal (MSc and PhD student) guided by senior researcher and statistical supervisor Carsten Hjorthøj (MSc, PhD) and principal investigator for Project Meaningful Activities and Recovery Lene Falgaard Eplov (MD, PhD). Siv Therese Bogevik Bjørkedal, Carsten Hjorthøj and Lene Falgaard Eplov are all employed at Copenhagen Research Center for Mental Health (CORE). CH is also an associate professor at the University of Copenhagen.

2. Introduction

2.1 Trial background and rationale

The background and rationale are described detailed in the protocol paper (Bjørkedal et al, 2020).

2.2 Objectives or hypotheses

From the protocol paper (Bjørkedal et al, 2020):

"The primary objective of this RCT is to determine whether MA&R in addition to standard mental healthcare is more effective than standard mental healthcare alone regarding activity engagement (POES-S) [38, 39] in a sample of individuals living with psychiatric disabilities. The intervention is being tested in addition to standard mental healthcare as it is an add-on to usual care. The second objective of this study is to evaluate whether MA&R in addition to standard mental healthcare is more effective than standard mental healthcare alone regarding outcomes related to activity engagement, e.g. functioning, personal recovery and quality of life"

3. Study Methods

3.1 Trial design

A multicenter two arm, parallel randomized controlled trial. Eligible participants where individuals with psychiatric disabilities, who were treated in one of three community mental health centers in Mental Health Center Copenhagen, or were citizens in the municipalizes of Copenhagen, Svendborg or Odense. Included participants were allocated with an 1-1 ration to either Meaningful Activities and Recovery (MA&R) a novel rehabilitation intervention, in addition to usual care, or usual care alone. The enrollment started at September 2018 and lasted to August 2020. MA&R lasts for about eight months and consists of 11 group sessions and 11 one-to-one sessions.

From the protocol (Bjørkedal et al, 2020)

"MA&R is delivered by a peer worker and an Occupational therapist. In addition to the planned sessions, the participants are offered individualized support to engage in meaningful activities. The

MA&R is a manualized intervention, with a workbook developed for the participants to support learning and personal exploration. MA&R utilized various methods such as didactic presentations, peer exchange, direct experiences with activities and personal exploration. The MA&R contains two courses: MA&R I and MA&R II which complement each other. In MA&R I, the participants can explore and identify meaningful activities, while MA&R II supports anchoring new activities and habits in everyday life."

Data was collected twice, baseline before randomization og at follow up, at the end of the intervention.

3.2 Randomization

From the protocol paper (Bjørkedal, et al. 2020):

After baseline data are obtained, the participants are randomly assigned to either the control (standard mental healthcare) or experimental group (MA&R + standard mental healthcare) with a 1:1 allocation using the randomization module in REDCap (Research Electronic Data Capture) [44, 45]. The randomization sequence was generated by a researcher employed outside the research team and entered to RedCap. The randomization is stratified by sex. Varying block sizes, unknown to the research team, are used. To ensure concealment, the randomization schedule is stored away from the research team and the block sizes are not disclosed. The allocation is performed by the researcher, who informs the participants and the counsellors and who assigns participants to the interventions."

Participants gave informed consent (verbal and written) and filled out the baseline questionnaire before randomization.

3.3 Sample size calculation

Below numbers are retrieved from the protocol paper (Bjørkedal et.al 2020).

- Type 1 error set at: 0.05 (α)
- Power: 0.80 (β)
- Difference in mean: 3 points
- within group standard deviation (SD): 6

From the protocol paper (Bjørkedal *et al.*, 2020): "The sample size is calculated based on the primary hypothesis to detect a minimal but clinically significant difference between the intervention group and the control group on POES-S (increased engagement in meaningful activities). In a recent RCT testing, the intervention Balancing Everyday Life (BEL) in a similar population as that in this study, Eklund et al. found a small effect of 1.4 points measured on POES-S (d = 0.27) [21]. As MA&R has a more comprehensive format (in terms of duration and costs) than BEL, the clinically significant difference between the study groups is set to 3 points, corresponding to a moderate effect size (Cohens d = 0.5). Based on the BEL trial, we assume the standard deviation in the study population to be 6. To achieve a statistical power of 80% and a significance level of 5%, a total of 128 participants must be included in this study; 64 in each group to detect this difference."

No interim analyses were planned.
There were no guidelines for stopping the trials early.

3.5 Timing of outcome measurements

Post interventions, about 8 months: Questionnaires were sent out 1-7 days after the last one-on-one session. There is no definite upper limit for when the follow-up data is not relevant anymore; however, the contact procedure included 6 contact attempts for 3-8 weeks. Generally, data was considered not relevant after three months after the questionnaires were sent out. Exceptions from this rule was made, if participants were hospitalized at the time for follow up (and wanted to answer the questionnaires after discharge), or participants needed help for filling out questionnaires and had to wait until the end of the first COVID -19 lockdown before being offered assistance.

4. Trial population

4.1 Eligibility criteria

This is described detailed in the protocol paper (Bjørkedal et al, 2020).

4.2 Information to be included in the CONSORT flow diagram

Numbers of persons referred, screened for eligibility, fulfilled inclusion/exclusion criteria (excluded), followed up (answered questionnaires), loss to follow-up (did not want to answer questionnaire, never answered questionnaire), retracted consent, analyzed according to intention to treat (ITT) analyses.

4.3 Withdrawal

4.3.1 Withdrawal from treatment

It was always possible to drop out of treatment/intervention. Hereafter one could choose to participate in follow-up (answer questionnaire etc.) or not. If a person in the intervention group dropped out of treatment this was registered (+ preferably reason if possible). If the participant was in the control group drop out of treatment as usual was not registered as it was not possible to get this information.

4.3.2 Withdrawal from research

It was always possible to drop out from research and thus not answer questionnaires at follow up. This was registered as e.g. *did not want to answer questionnaire/loss to follow-up* if the participant explicitly communicated this to the project, otherwise unspecified reason to dropout (e.g. *not possible to get in touch with participant/loss to follow-up*) was registered.

According to Danish law it is possible for participants to withdraw their consent and have all person sensitive data deleted. In these cases, data cannot be used in analyses. In these instances, we will keep the randomization result and projects specific ID (not identifiable CPR number) in the database. Dropout from research (loss to follow-up and withdrawn consent) is summarized at 8 months follow-up.

4.4 Baseline characteristics

Sex, age, housing/marital status, educational level, diagnosis, work status, functional level (assessed by researcher). Register-based and self-reported baseline outcome measures will also be summarized.

5. Statistical principles and analysis

5.1. Confidence intervals and p-values

The two-sided significance level for statistical tests will be 5 %. Differences in means and proportions will be presented with a 95% confidence interval (CI) and a p-value. All primary, secondary and exploratory measures will be presented.

5.2 Adherence

Participant adherence to the MA&R is not defined as a minimum number of sessions that the participants have participated in. MA&R combines group sessions, individual sessions and individualized support. Participation in group and one-on one session will be reported separately for the type of session and totally for the sessions together. Amount of individual support received measured in hours will be reported. MA&R is delivered in an individualized manner, which means that each MA&R course is tailored to each participant. Hence, the amount of support and session participated in, may vary extensively from participant to participant.

Fidelity to the MA&R intervention and its principles is evaluated through fidelity reports. Fidelity to MA&R will be described as a result of one or more fidelity reports (i.e. poor, good or excellent fidelity to the model).

Major deviations (i.e. outcome changes etc.) from this SAP will be presented/summarized in the reporting of results.

5.3 Specification of outcomes and timing

See appendix 1 for an overview over outcomes and timing.

- Activity engagement (measured by POES-S) at eight months follow up is the primary outcome (end point comparison)
- Personal recovery (measured by QPR), quality of life (measured by MANSA) and levels of functioning (measured by WHODAS-12) at eight months follow up are secondary outcomes (end point comparisons)
- WHODAS-36 subscales, WHODAS-36 total score and health related quality of life (EQ-5D-3L) at eight months follow up are exploratory outcomes (end point comparison).

5.4 Analysis methods

The trial is analyzed according to the statistical principle “intention-to-treat”. This means that analyses are based on all included participants as opposed to “per protocol” analyses.
For the primary outcomes in both trials, the null hypothesis tested is that there is no difference in activity engagement between the two groups (intervention group and control group) at 8 months’ follow-up. The null hypotheses are similar in the other analyses assuming no differences between groups.

5.4.1 Baseline variables

The chi^2 test is used to test for differences in nominal baseline variables (sex, education, housing status, marital status, diagnosis, employment status) and the t-test is used to test for differences in ordinal/continuous baseline variables (age, activity engagement, functioning, personal recovery, quality of life). If the test assumptions in the latter are not met, a non-parametric test will be performed instead (e.g. Kruskal Wallis or Mann Whitney U test).

5.4.2 Self-reported outcomes

Primary, secondary and exploratory outcomes are calculated and presented in means of scores at 8 months follow-up. In the protocol we wrote:

"The main outcome measure is activity engagement, measured by POES-S. To test the research hypothesis, the differences between the intervention group and the control group will be analyzed using ANOVA to determine the statistical significance. Effect sizes to judge clinical relevance will be calculated by Cohen's d. In accordance with the intention-to-treat principles,

"multiple multivariate imputations" will be used and all co-variates of supposed prognostic significance will be used to impute a distribution of missing data.

The continuous power measurements will be analyzed with a repeated measurement model in mixed model analyses with unstructured variance. The prerequisite for using this analysis and for the use of multiple imputations is that data are missing at random or data missing completely at random as opposed to non-ignorable nonresponse. This distinction is important as repeated measurements and multiple imputations are both models based on a statistical estimation of non-existent responses, and the prerequisites for this estimation must be met for the analyses to be valid." (Bjørkedal et al, 2020)

5.5 Sensitivity analyses

No adjustments will be made in the primary analyses other than for stratification variables.

Sensitivity analyses are made with:

- Adjustment for baseline differences for those baseline characteristics with unequal/skewed baseline means and that can thus be associated with the outcome. Baseline characteristics in this case include (in addition to stratification variables) diagnosis, age, site and functioning) and self-reported outcome measures at baseline. Baseline tests will not be used exclusively in judging whether to include in the sensitivity analysis. Inclusion will be based on whether the groups are different to the extent that it could affect the analyses. The selection will be guided by CH.
- Imputations of missing values representing "worst" and "best" case of imputations. We will make two analyses: one where we in both groups replace imputations with "worst" case defined as the 90 percentiles from the imputed value and one where we in both groups replace imputations with "best" case defined as the 90 percentiles from the imputed value.
- The observed data.

Sensitivity analyses will be made for the primary outcome.

5.6 Subgroup analyses

No subgroup analyses will be planned, as the sample size does not allow this.

5.9 Missing data

Multiple imputations will be used to address the issue of missing data. If possible, multiple multivariate normal regression imputations (Markov Chain Monte Carlo (MCMC)) will be used. This is possible if all imputed data follow the same distribution (e.g. are scale variables). A table of auxiliary variables are made based on the list of variables used in the MA&R project. These are chosen for being theoretically associated with the specific outcome. Also, variables that are predictive for missing data are included. This selection will be based on whether there is skewed dropout for the specific outcome variable. In the cases of extreme distributions predictive mean matching will be used instead of multivariate normal imputations. All variables in the model will also be included in the imputation model. We will perform at least 100 imputations for each analysis.

5.10 Additional statistical analyses

Additional to the planned analyses in the protocol we will:

- Calculate the effect size (based on Cohen's d) of the primary outcome POES- S at 8 months follow up.

5.11 Safety data

The following variables will be summarized for each randomization group at 8 months follow-up.

- Number of bed days and admissions (somatic indication)
- Number of bed days and admissions (psychiatric indication)
- Number of somatic outpatient visits
- Number of deaths from suicide and other causes
- Scores of The Clinical Global Impression – Severity of Illness Scale (CGI-S)

5.12 Statistical packages to be used to carry out analyses

We will primarily use the statistics program SPSS. Other statistical packages might be used for some analyses.

6. Appendix 1

Table 1. Overview of outcomes

Outcome measure no	Outcome	Source	Outcome measure	Definition of outcome and calculation	Variable properties	Higher/lower score indicates better outcome	Collected at 8-months follow-up
#1	Primary	Self-reported	Activity engagement (POES-S)	Calculated and presented as mean sum of points/scores	Numerical variable. 9 items. Items rated: 1-4. Scale from 9-36	Higher	x
#2	Secondary	Self-reported	Functioning (WHODAS – 12 items)	Simple scoring or Complex scoring (ITEM RESPONSE THEORY) Computer program available from WHO website Calculated and presented as mean sum of points/scores	Numerical variable. 12 items. Items rated: 1-5. Scale from 12-60 Metric range from 0 -100	Lower	x
#3	Secondary	Self-reported	Recovery (Questionnaire about the processes about recovery (QPR) 15 item)	Calculated and presented as mean sum of points/scores	Numerical variable. 15 items. Items rated: 0-4. Scale from 0-60	Higher	x
#4	Secondary	Self-reported	Quality of life (Manchester short assessment of quality of life (MANSA))	Calculated and presented as mean sum of points/scores.	Numerical variable. 12 items. Items rated: 1-7. Scale from 12-84	Higher	x
#5	Secondary	Self-reported	Health-related quality of life (EQ-5D-3L)	Calculated and presented as a weighted mean on a scale	Numerical variable. 5 items. Each combination of answers on items is provided with a weight/number between 0-1.	Higher	x
#6	Explorative	Self-reported	Functioning (WHODAS 2.0 36 items	Simple scoring or Complex scoring	Each item rated 1-5 Total scale score: 36-180	Lower	x

			(domain score and total score))	Calculated and presented as a mean sum of points/scores	Domain scale score: Each domain contains between 5 to 8 eight items. (complex scoring) metric range 0-100		

Table 2. Safety measures

Safety measure no.	Outcome measure	Source	Definition of outcome and calculations	Variable properties
1	Number of outpatient somatic visits from baseline to follow-up	Register	Number of visits are calculated as an incidence rate ratio based on the follow-up period. Total number is also presented.	Numerical variable. Minimum: 0 visits, no defined upper limit
2	Number of inpatient somatic bed days and admissions from baseline to follow-up	Register	Number of bed days and admissions are calculated as incidence rates and an incidence rate ratio based on the follow-up period. Total number is also presented.	Numerical variables. Minimum: 0 bed days, no defined upper limit
3	Number of inpatient psychiatric bed days and admissions from baseline to follow-up	Register	Number of bed days and admissions are calculated as an incidence rate ratio based on the follow-up period. Total number is also presented.	Numerical variables. Minimum: 0 bed days, no defined upper limit
4	Deaths from suicide and other causes from baseline to follow-up	Register	Total number of deaths is reported + stratified by cause of death: suicide and other	Numerical variable. Minimum: 0 deaths, upper limit is the total number of included participants
5	Symptoms severity (Clinical Global Impression – self report)	Self-reported	Calculated and presented as mean sum of points/scores	Numerical variable. 1 item, item rated 1-7 (Scale from 1-7)

7. References

Bjørkedal STB *et al*. (2020) Meaningful Activities and Recovery (MA&R): the effect of a novel rehabilitation intervention among persons with psychiatric disabilities on activity engagement—study protocol for a randomized controlled trial, *Trials* (2020) 21:789

Gamble, C. *et al.* (2017) 'Guidelines for the content of statistical analysis plans in clinical trials', *JAMA - Journal of the American Medical Association*, 318(23), pp. 2337–2343. doi: 10.1001/jama.2017.18556.

APPENDIX IV

Updated literature search

Results from the updated literature search

Table 1: Updated overview over systematic reviews investigating the effectiveness of occupational therapy interventions in mental health

Author, year and country	Aim	Method	Results	Intervention	Evaluation
Arbesman and Logsdon (2011) USA	To investigate research literature evaluating the effectiveness of interventions within the scope of occupational therapy, on employment and education for people with serious mental illness	Inclusion criteria were Peer-reviewed papers published after 1990. Severe mental illness, age 18–65 year, with Evidence Level I (i.e. randomised controlled trials, systematic reviews, and meta-analyses), Level II (i.e., non-randomised controlled trials such as cohort studies), and Level III (ie, pre-test/ post-test, one-group designs)	46 articles were included. Supported employment and vocational rehabilitation: evidence is strong especially Individual Placement and Support Supported Education Programs: supported education programs at the post-secondary level are effective, in addition supported employment plus cognitive or social skills training showed good effect	Occupation- and activity-based interventions Interventions addressing performance skills, aspects of the environment, activity demands, and client factors Work, education and homemaking, parenting and environmental support programs	Studies included, at evidence level 1–3 Interventions focus on work, education and home skills
Bullock and Bannigan (2011) England	To investigate the effectiveness of activity-based group work on functioning and symptom reduction for people	Search strategy included electronic searching, hand searching, citation searching, and use of grey literature. No time limit for the search	3 articles included Findings showed that activity-based group work was more effective than verbally based group	Activity-based group works focus on skills development and/or encouragement of participation in social interactions.	Three studies included, level 2–3 of evidence. Heterogeneity and flaws in quality meant it was not possible to make

	with severe and enduring mental illness in community settings.	.	work, on social interaction outcomes. No evidence were found to illuminate effectiveness of activity-based group work on functioning or symptom reduction.		specific inferences for practice from the studies Older studies were included Limited to activity-based group work interventions
Gibson et al (2011) USA	To investigate research literature evaluating the effectiveness of occupational therapy interventions on recovery in the areas of community integration and normative life roles for people with serious mental illness	Peer-reviewed studies published since 1990 Adults (18-65 years) with severe mental illness. Interventions within the scope of occupational therapy practice; Studies at evidence level 1–3. Search terms for intervention were: instrumental activities of daily living, education and work	52 articles included Evidence exists to support efficacy of occupational therapy interventions focused on components of recovery from serious mental illness Moderate to strong evidence exists for social skill training and supported employment. Moderate evidence for effectiveness of interventions in other areas, including instrumental activities of daily living, training, supported education and neurocognitive training	Interventions included social participation, instrumental activities of daily living (IADL) work and education intervention, neuro-cognitive training, client-centered, Context and Environment - centered	Studies included, at evidence level 2–3 A variety of interventions were tested
Ikiugu et al	To estimate the effectiveness of	Inclusion criteria: participants aged	11 studies were included.	Theory-based occupational	The PRISMA protocol and the CONSORT

Results from the updated literature search

(2017) USA	theory-based occupational therapy interventions on occupational performance and wellbeing among people with a mental health diagnosis	≥18 years); with mental health diagnosis; randomised controlled trial design. Wellbeing, occupational performance, or both as dependent variables. Parametric statistics were used to analyses data. Literature search period: 1995 - June 2016	Results indicated a medium effect of interventions on improving occupational performance (mean Hedge's g 5 0.50, Z 5 4.05, P<0.001) and a small effect on wellbeing (mean Hedge's g 5 0.46, Z 5 4.96, P<0.001)	therapy interventions were guided by the behavioral/ cognitive conceptual practice model, The Canadian model of Occupational Performance and Engagement the Cognitive Disabilities model, unspecified client-centered models, or the psychodynamic model	checklist were applied to assess methodological quality and risk of bias. Of the 11 studies, randomization was concealed in 6, researchers or participants were blinded in none, and data collectors were blinded in 4.
D´Amico ML et al (2018) USA	To evaluate the evidence for the effectiveness of interventions within the scope of occupational therapy on performance and participation for people with serious mental illness.	Databases searched included MEDLINE, PsycINFO, CINAHL, OTseeker, and the Cochrane Database of Systematic Reviews. Citations, abstracts, and full-text articles were read and assessed for inclusion and analysis.	61 articles were included. Strong evidence was found for psychoeducation and occupation- and cognitive-based interventions. Moderate evidence for skills-based interventions. Limited evidence exists for technology-supported interventions.		
Noyes S et al (2018) USA	To identify evidence for the effectiveness of interventions that occupational therapist can provide to assist	Citations, abstracts, and full-text articles in databases including MEDLINE, PsycINFO, CINAHL, OTseeker, and	Fifty-seven articles met criteria for inclusion. For employment, strong evidence was found for the Individual		

Results from the updated literature search

	people with severe mental illness with employment and education.	the Cochrane Database of Systematic Reviews were reviewed for inclusion and analysis.	Placement and Support (IPS) model and cognitive interventions. For education, moderate evidence was found for supported education interventions		
Morris K et al (2018) UK	To compare the effects of occupational therapy delivered by occupational therapists to occupational therapy delivered by any other person for people with schizophrenia.	The Cochrane Schizophrenia Group's Study-Based Register of Trials (including trial registers) where searched. Search ended July 2018. Inclusion criteria were randomised controlled trials comparing the functional or clinical outcomes of occupational therapy, for people with schizophrenia delivered by occupational therapists with occupational therapy delivered by anyone other than occupational therapists. Review authors independently inspected citations, selected studies, extracted data, and appraised study quality	The search yielded 1633 records. 17 full-text reports (14 studies) were selected for inspection, and subsequently excluded because they did not meet the inclusion criteria.	Not applicable, since no studies were included in the systematic review	
Christie L et al (2021) UK	To answer the question: "*Does occupational therapy improve function and participation in activities of everyday life in adults with a*	The search strategy was guided by PICO: P: adults with a primary diagnosis of depression. I: interventions aiming to enable participation daily life activities, delivered by an occupational therapist, to	6 full-text articles were included. four were RCTs, one a qualitative study and one a mixed methods study. The studies were from Canada, Germany, the Netherlands, Taiwan,	Three Return-to-work interventions combining group and individual sessions, one handcraft intervention (e.g. woodcraft or art), one writing intervention and one lifestyle intervention,	

	diagnosis of depression? "	enhance well-being and participation. C: no occupational therapy O: change in occupational performance, level of function or participation in activities of everyday life or change in satisfaction in these. AMED, CINAHL, The Cochrane Library, EMBASE, MEDLINE, PsycINFO and OT Seeker were searched, in 2017 and repeated in 2019. Studies were subject to critical appraisal and methodological quality assessments, using various standardized approaches, e.g., the CASP guidelines.	and the United Kingdom, representing a total of 374 participants. Strong evidence was found for the effectiveness of occupational therapy return to work (RTW) interventions in improving depression symptomology. Limited evidence exists for the effectiveness of occupational therapy RTW interventions in improving work participation. Limited evidence (only one study) was found for the effectiveness of occupational therapy lifestyle interventions for reducing anxiety and suicidal ideation.	teaching to improve performance/ lifestyle, interpersonal skills, illness/stress management.	
John A et al (2022) India	To answer the question: "*Do instrumental activities of daily living (IADL) interventions improve functional outcomes in persons with Schizophrenia?"*	A systematic search for all RCTs investigating the effectiveness IADL interventions on functioning in persons with Schizophrenia published from 1992 till 31st December 2020, in the following databases: the	Nine RCTs were included in the review, representing a total of 655 participants with schizophrenia spectrum disorders. Age ranged from 16 to 74. Four of the studies were conducted in the USA –	Interventions included life skills training (e.g., grocery shopping, money management), psychoeducation, cognitive behavior therapies and social skills training. The training mode included role-plays, videos,	Studies included were at evidence level I.

		following databases: Google Scholar, PubMed, Science Direct, ProQuest and EBSCO. Inclusion criteria were RCTs that examined interventions facilitating independent living skills (e.g., cooking) psychoeducation, along with some components of cognitive behavior therapy and social skills. The primary outcome was functioning. Trials were assessed against quality criteria, e.g. random sequence generation, blinding etc. Risk of bias was assessed according to the revised Cochrane risk-of-bias tool for randomized trials and papers categorized the into low, some concerns or high risk of bias.	and one in Israel, Spain, China, Turkey, and South Korea. The results showed moderate to strong evidence for skills training, either behavioral or social skills.	demonstrations, homework assignments, individual counseling sessions, and group discussions. Some of the modules had practical workbooks and instructions. Two studies included involvement of family members and one study included real-life training.	

Table 1: An updated overview of systematic reviews of the effectiveness of occupational therapy interventions in mental health between 2003 and 2022.

Results from the updated literature search

Author, year and country	Aim	Design	Participants	Intervention	Outcome	Outcome measures	Evaluation
Buchain et al (2003) Brazil	To investigate the effectiveness of occupational therapy in addition to clozapine	RCT	26 patients with treatment resistant schizophrenia	The occupational therapy intervention consisted of free choice of activities was used both individually and group activities	Combination of occupational therapy and clozapine showed to be more effective than the use of clozapine alone	The Scale for Interactive Observation in Occupational Therapy	Level 3 Small sample size Blinding not mentioned No p-value reported
Cook et al (2009) UK	To investigate the effectiveness of occupational therapy for people with psychotic	Pilot RCT	42 participants with schizophrenia or psychosis	Individualised occupational therapy up to 12 months in two	Occupational therapy group showed clinically significant improvements,	Social functioning scale, assessment of negative symptoms	Level 3 Pilot RCT and qualitative methods Community setting

Results from the updated literature search

	conditions			community mental health settings, compared to treatment as usual			Small sample size No power calculation Low confidence interval
Gutman et al (2009) USA	To assess the effectiveness of a supported education program for adults with psychiatric disabilities	Quasi-experimental design	38 participants with psychiatric disabilities	Supported education Services, delivered as The Bridge Program ran twice a week for 6 weeks in the occupational therapy programme	The intervention helped participants to increase their skill level in basic academic areas, improve professional behaviour and social skills needed for school and work settings, and gain the confidence to test their skills	The Student Role Scale, The Task Skills, Interpersonal Skills, and School Behaviour Scales, Participant Overall Satisfaction Scale	Level 3 Quasi-experimental design Small sample size 1 year follow-up planned No information about the control group
Lambert et al (2010) UK	To assess the cost effectiveness of an occupational therapy-led lifestyle approach to treating panic disorder in primary care compared with	Randomised controlled trial study and economic evaluation	170 adults with panic disorder	The intervention addressed diet pattern, fluid intake, exercise and habitual lifestyle drug use (caffeine, alcohol and nicotine)	If the maximum willingness to pay per additional quality adjusted life years is £30 000, then there is an 86% chance that a lifestyle intervention may be	Beck anxiety inventory Quality adjusted life year: the EQ-5D (EuroQoL) questionnaire	Level 2 Randomised controlled trial Unblinded staff and participants Economical evaluation included

Results from the updated literature search

	routine general practitioners' care				considered to be value for money over 10 months		
Poon et al (2010) China	To examine the vocational outcomes of young people with early psychosis after participation in occupational therapy program.	Survey with follow-up	147 Patients between 15 and 25 years of age, early psychosis or schizophrenia	Symptom management, work, habit training, enrichment of the work experience, building social support	Retrospective review of case management plans and outcomes, 53.7% of the patients were engaged in productive roles (vocational training, working, or studying) 3 months after discharge from the occupational therapy program.	Counting who is in productive roles and who is not	Level 3 Survey with follow-up Retrospective and exploratory study design No control groups
Tatsumi et al (2011) Japan	To determine whether occupational therapy can improve the interpersonal relationships and negative symptoms in hospitalized patients	Small scale RCT	38 hospitalized patients with schizophrenia and severe negative symptoms for more than 10 years	Occupational therapy group participated in cooking activities once a week for 15 weeks. The intervention had three elements: participation, goal setting and stepwise performance. goal; and doing the activities step by step	No significant differences were found between the intervention group and the control groups.	Scale for the Assessment of Negative Symptoms, the Brief Psychiatric Rating Scale, the Rehabilitation Evaluation Hall and Baker scale The Profile of Mood States scale Seating preferences	Level 3 Small sample size (n=38) Insufficient description of intervention.

Results from the updated literature search

Katz and Keren (2011) Israel	To compare the effectiveness of occupational goal intervention in clients with schizophrenia to the Frontal Executive Programme and a control group	Quasi-experimental design	18 patients with schizophrenia or schizoaffective disorder Age 20–38 years	Occupational goal intervention and strategy learning using activities and everyday tasks for 6–8 weeks: (1) food preparation (2) money management (3) reading, writing, and using computers for information. Frontal Executive Programme involves training for neurocognitive rehabilitation based on a process-specific approach Consists of three modules (cognitive shift, working memory, and planning)	No significant differences among the three groups Significant differences within groups before and after intervention and moderate to high effect sizes The occupational goal intervention group showed relative improvement on all measures, activity, and participation	Wisconsin Card Sorting Test. Wechsler Adult Intelligence Scale— Digit Span Forward and Backward Behavioural Assessment of the Dysexecutive Syndrome Executive Functions Performance Test and Instruments: Activity and participation Outcome Measures	Level3 Quasi-experimental with 6 months follow-up Small sample size (n=18) High drop-out rate (50 %) Blinding not mentioned
Edgelow and Krupa (2011) Canada	To assess the efficacy and utility of Action over Inertia, an occupational time-use intervention to enhance	Pilot RCT	18 people with serious mental illness, living in the community	Intervention content: Determining for change, reflecting o occupational balance and engagement	Treatment group participants increased their occupational balance, in average of 47 minutes more	Profiles of Occupational Engagement for People With Schizophrenia were collected from	Level 3 Pilot RCT Small sample size Blinding not mentioned

	occupational balance and engagement			patterns, information about mental illness and occupational balance and engagement Goal planning and support, monitoring and refinement of plans	per day in activity compared to the control group	24-hour diaries	
Yamashita et al (2012) Japan	To investigate the effects of single and repeated occupational therapy on psychiatric symptoms.	Follow-up study	215 participants with psychiatric symptoms (152 inpatients and 63 outpatients)	Art therapy, crafts, pottery, sports, calligraphy, horticulture, cooking and music planned in 25 sessions	Short-term effect where shown, whereas repeated psychiatric occupational therapy cannot induce long-term effect on psychiatric symptoms	Psychiatric symptoms measured: Depressive mood, tension, irritability Anxiety and fatigue reported before and after each psychiatric occupational therapy by applying a Visual Analogue Scale	Level 3 Follow-up study design Insufficient description of intervention Non-validated outcome measures Large drop-out rate No control groups
Chapleau et al (2012)	To provide occupational therapy consultation to stabilize or improve housing status and achieve client goal attainment	Repeated measure experimental design	57 people with severe mental illness who were homeless or at risk of homelessness	The use of an occupational therapy consultation model embedded in a case management program for people who are homeless	Significant improvement in housing stability and goal attainment	Allen Cognitive Level Screening Device and Canadian Occupational Performance Measure and housing scales	Level 3 Follow-up study design Not randomised Small sample

Results from the updated literature search

Schindler and Sauerwald (2013) USA	To examine outcomes of the first 4 years of an occupational therapy program utlizing principles of supported education and employment (The Bridge program)	Quantitative one-group pre-test–post-test survey design and qualitative focus groups	48 patients with various psychiatric symptoms	Client-centered, occupation-based supported education and employment program	Increased client scores on satisfaction and performance of occupational performance problems. Participants reported that they improved in 95–100% of goals they established	Canadian Occupational Performance Measure	Level 3 Survey study design Small sample size No comparison group
Foruzandeh and Parvin (2013) Iran	To investigate the effects of occupational therapy on symptoms in patients with schizophrenia	Survey study	60 Patients diagnosed with schizophrenia	Participants were divided randomly into intervention and usual treatment groups (30 patients in each group). Intervention included: art therapy, crafts, pottery, sports, calligraphy, horticulture and music	Participation in activities seems to have a short-term effect on psychiatric symptoms	A scale for the assessment of positive and negative symptoms	Level 3 Survey study design Small sample size
Hoshii et al (2013) Japan	To compare the therapeutic effects of subject-chosen and therapist-chosen activities in occupational therapy for inpatients	Prospective comparative study	59 patients diagnosed with schizophrenia	6 months' occupational therapy, participating in either activities of their choice (subject-chosen activity group, n=30) or activities	Suspiciousness and hostility scores and preoccupation scores of the general psychopathology scale improved significantly in the subject-chosen	The Positive and Negative Syndrome Scale and the Global Assessment of Functioning Scale were used to evaluate	Level 3 Comparative study design Small sample size

Results from the updated literature search

	with schizophrenia			chosen by occupational therapists based on treatment recommendations and patient consent (therapist-chosen activity group, n=29)	activity group compared with the therapist-chosen activity group. No significant differences in psychosocial functions between the two groups were found	psychiatric symptoms and psychosocial function	
Hees et al (2013) Netherlands	To evaluate whether adjuvant occupational therapy can improve the effectiveness of treatment as usual	RCT	117 participants sick listed workers with major depression	The intervention consisted of 18 sessions (9 individual sessions, 8 group sessions and a meeting with the employer) Intervention was conducted by two experienced occupational therapists who were trained in the intervention protocol	The groups did not significantly differ in their overall work participation The intervention group had greater improvement in depression symptoms, an increased probability of long-term symptom remission, and return to work in good health. Intermediate outcomes were work-related, coping and self-efficacy	Work participation (hours of absence and duration until partial/full return to work) and depression, at-work functioning, and health-related functioning	Level 2 RCT Large sample size Intervention protocol
Eklund et al (2014) Sweden	To investigate the effectiveness of a tailor-made intervention to improve day	Cluster RCT	108 participants, recruited from the	Intervention consisted of three steps: 1: Users and staff in all units filled	There was no difference between the intervention	Satisfaction with Daily Occupations A specific questionnaire	Level 2 57 in the intervention group Tailor made

Results from the updated literature search

	center services specifically tailored for each day center.		participating day centers	out a questionnaire about perceived Meaningfulness in Day Centers 2: An education and workshop for staff 3: Goal setting for improving services	group and the comparison group, regarding change in perceived meaningfulness	developed to measure the center's ability to generate meaningful occupations for the attendees	intervention
Chen et al (2015) Taiwan	To examine the efficacy of the Life Adaption Skill Training program for individuals with depression	Single-blinded RCT	68 adults with depressive disorders	Life Adaption Skill Training was manualized program aiming to enhance wellbeing through occupational participation with different strategies and skills. It contained 24 group sessions of 1.5 hour, twice a week for 12 weeks	Significant incremental improvements with moderate to large between-group effect sizes on level of anxiety and level of suicidal ideation in the intervention group compared to the control group	The primary outcome measure World Health Organization Quality of Life-BREF-Taiwan version. Secondary outcome measures Occupational self-assessment, the Mastery scale, the Social support questionnaire, the Beck anxiety inventory, the Beck depression inventory-II, and the Beck scale for suicide ideation	Level 2 Small sample size Large drop-out rate
Shimada et al (2016)	To examine the	Quasi-experimental	51 patients with	Program content:	Participants showed	Brief Assessment of Cognition in	Level 3

Results from the updated literature search

Japan	effectiveness of an individualized occupational therapy program	controlled trial	schizophrenia or schizoaffective disorder between 20 and 65 years	Motivational interviewing Self-monitoring Individualized visits Handicraft activities Individualized psychoeducation Discharge planning Activity-oriented group treatment	significant improvement on verbal memory, working memory, verbal fluency, attention	Schizophrenia (Japanese version)	
Lipskaya-Velikovsky et al (2016) Israel	To investigate the effectiveness of a short term intervention program, ”Occupational Connections”	Pre-post pilot study	10 people with schizophrenia	The intervention aimed to encourage development of the understanding and expansion of positive occupational experiences and engagement in meaningful occupations. It focused on occupation-related needs and skills (reflecting its occupational orientation), with respect to each participant`s personal interests, values, needs	Participants showed a greater tendency toward cognitive improvement, participation diversity, satisfaction, and enjoyment and participation intensity	Observed Tasks of Daily Living, Adult Subjective Assessment of Participation, Schizophrenia Quality of Life Scale, Positive and Negative Syndrome Scale, Letter–Number Sequencing Test Trail Making Test, Neurobehavioural Cognitive Status Examination Rey-Osterrieth, Complex figure test Category Fluency Test	Level 3 Small sample Quota sampling

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				and experiences			
Wisenthal et al (2016) Canada	To evaluate the effectiveness of cognitive work hardening in preparing people with depression to return to work.	A single group pre-test–posttest study design (mixed method)	21 participants with depression	Intervention was provided in a simulated (office) work environment. Method delivery included: Education Roleplays Coaching, Goal setting	Work ability, fatigue, and depression severity were significantly improved postintervention	Work Ability Index Multidimensional Assessment of Fatigue Beck Depression Inventory II	Level 3 Small sample No control group.
Vizzotto et al (2016) Brazil	To test the efficacy of the Occupational Goal Intervention method	Pilot RCT	25 patients with treatment resistant schizophrenia	The Occupational Goal Intervention targets executive functions by using learning strategies to improve everyday functioning.	Significant statistical differences, favoring intervention group on the Behavioural Assessment of the Dysexecutive Syndrome test, both in sub test and the total score	The Direct Assessment of Functional Status The Independent Living Skills Survey Wechsler Abbreviated Intelligence Scale	Level 3 Small sample
Eklund et al (2017) Sweden	To evaluate the effectiveness of the 16-week Balancing Everyday Life program, compared to care as usual, for people with mental illness in specialised and community	Cluster RCT	133 participants and control group of 93 participants with psychiatric disabilities, recruited from community mental health centers and	Balancing Everyday Life (BEL): a group-based program (5–8 participants) consisting of 12 sessions, one session a week, and 2 booster sessions with 2-week intervals	The BEL group improved more than the care as usual group from baseline to 16 weeks on activity engagement, activity level and activity balance.	Profiles of Occupational Engagement for People With Severe Mental Illness Global assessment of Functioning (GAF-S and GAF-F)	Level 2

Results from the updated literature search

	based psychiatric services		outpatient services.	Themes for sessions: activity balance meaning and motivation healthy living work-related activities leisure and relaxation social activities	The BEL group also improved significantly on the secondary outcomes of symptom severity and level of functioning from baseline to 16 weeks.	Satisfaction with Daily Occupations	
Shimada T el al (2018) Japan	To investigate the feasibility and effectiveness of an individualized occupational therapy program (IOT) on cognitive and social functioning, intrinsic motivation, medication adherence, symptoms, and treatment satisfaction in patients with schizophrenia. The IOT was being investigated as an add-on to group based	A multicenter, open-labeled, blinded-endpoint, RCT	Participants were 136 recently hospitalized patients in a psychiatric hospital; with a diagnosis of schizophrenia or schizoaffective disorder	The IOT was developed to facilitate proactive participation in treatment and improve cognitive functioning and other outcomes for patients hospitalized with acute schizophrenia. Program components included motivational interviewing, self-monitoring, individualized visits, handicraft activities, individualized psychoeducation,	Participants in the GOT + IOT demonstrated significant improvements in client satisfaction, cognitive functioning, perceived choice, interests/enjoyment and values and interests compared with GOT only, corresponding to a small or moderate effect size, depending on the outcome	Brief Assessment of Cognition in Schizophrenia Japanese version (BACS-J), the Schizophrenia Cognition Rating Scale Japanese version, the Social Functioning Scale Japanese version, the Global Assessment of Functioning scale, the Intrinsic Motivation Inventory Japanese version (IMI-J), the Morisky Medication Adherence Scale-8 (MMAS-8), the Positive and Negative	Level 2 Multi-center trial Sample size calculation to ensure adequate power. Assessor blinded.

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	occupational therapy (GOT)			and discharge planning		Syndrome Scale (PANSS), and the Japanese version of Client Satisfaction Questionnaire-8 (CSQ-8J).	
Gunnarson B et al (2018) Sweden	To compare the Tree Theme Method® intervention with regular occupational therapy on activities in everyday life, symptoms of depression and anxiety and psychological outcomes.	A prospective parallel group RCT	121 Participants between 18 and 65, with anxiety or depression and problems with everyday life, recruited from primary health unit centers, and outpatient mental health care units	Life story telling, reflective dialogue with the occupational therapist, relaxation, painting trees representing different periods in the participant lives.	No significant differences in short term outcomes were found between the groups. Both groups showed positive significant outcomes regarding almost all aspects of activities in everyday life, psychological symptoms, and health-related and intervention-related aspects.	Canadian Occupational Performance Measurement (COPM), Satisfaction with Daily Occupations (SDO), Occupational Balance Questionnaire (OBQ), Client Satisfaction Questionnaire (CSQ), Symptom Checklist-90-R (SCL-90-R), Montgomery-Åsberg Depression Rating Scale (MADRS-S), Hospital Anxiety and Depression Scale (HADS), Sense of Coherence Scale (SOC), Manchester Short Assessment of quality of life	Level 2 Multi-center trial with a pragmatic design Sample size calculation to ensure adequate power

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						(MANSA), Helping Alliance questionnaire (HAq-II)	
Shimada T et al (2019) Japan	To examine the effect of individualized occupational therapy (IOT) compared to usual group occupational therapy (GOT) on the rehospitalization of patients with schizophrenia over a two-year period.	A prospective cohort study	Patients with schizophrenia who were discharged within 1 year from a psychiatric hospital	The IOT utilized a combination of motivational interviews, self-monitoring, visits, craft activities, psychoeducation, and discharge planning, delivered in an individualized manner.	Significantly fewer patients (P=0,000) who received GOT + IOT were hospitalized at the end of the 2-year follow-up period, compared to GOT alone (16 vs 40)	Hospitalization	Level 3 The analysis did not include participants hospitalized more than a year. The study population represent a selected sample (willing to be included in an RCT)
Mashimo I et al (2020) Japan	To examine the effects of home-visit occupational therapy (OT) using a Management Tool for Daily Life Performance (MTDLP), designed to support patients in completing their desired daily life activities,	A multicenter RCT	60 participants with schizophrenia spectrum disorders, who utilized one of the 20 psychiatric outreach teams in Japan	For both the intervention and control group, one attending occupational therapist per participant provided interventions once a week, for between 30 minutes to 1 hour, for four months. MTDL was a tool consisting of work sheets, where the OT and	At post intervention assessment follow up both groups showed higher scores on the GAF. The GAF scores of the MTDLP group significantly improved as compared to the control group.	The Global Assessment of Functioning (GAF) and the Social Functioning Scale (SFS).	Level 2 No sample size calculation to estimate power. No information about randomization, allocation sequence or blinding of assessors

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	compared to home-visit OT without using MTDL			the participants' asses desired daily life activities, inhibitors for performing those, and planned a rehabilitation program based on the International Classification of Functioning, Disability, and Health (ICF)			
Kim Y et al (2020) South Korea	To investigate the effects of a grocery shopping training (GSSE) program in real environments on the executive functioning and instrumental activities of daily living (IADL), in people with schizophrenia	A nonequivalent control group pretest-posttest design.	A total of 20 patients with schizophrenia were recruited at the mental-health welfare center in South Korea, participants were between 18 and 55 years, and with no severe psychiatric disability (GAF > 50)	Eight sessions of four hours delivered twice weekly. Intervention components included strategies guiding memory when searching for groceries, time for shopping and generalization of skills by practicing in a real environment	At post-intervention assessments, differences between groups were found, in improvement In cognition, executive functioning and IADL, favoring the intervention group.	The Korean version of the Executive Function Performance Test (EFPT-K), d the Korean Instrumental Activities of Daily Living (K-IADL), the Korean version of the Montreal Cognitive Assessment (MoCA-K)	Level 3 Small sample size, no blinding of assessors.
Vizzotto et al (2021) Brazil	To test the efficacy of the Occupational Goal Intervention in people with Treatment	A single blinded randomized controlled trial	Participants were people between 18 and 55 with Treatment Resistant Schizophrenia		The OGI group improved significantly compared with the control group, with medium to large effect sizes in	The Behavioral Assessment of the Dysexecutive Syndrome, the Direct Assessment of Functional Status–Revised	

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	Resistant Schizophrenia		according to *DSM V*.		posttreatment scores on the BADS and DAFS–BR. The ILSS–BR showed the highest effect sizes at posttreatment and follow-up	(DAFS–BR), and the Independent Living Skills Survey (ILSS–BR), administered to caregivers.	
Seoane-Bosaz M et al (2022) Spain	To evaluate the feasibility and outcomes of an occupational therapy program consisting of aquatic-based activities (AA-OT program).	A pilot RCT	16 participants age ≥ 18 years, with a diagnosis of SMI, had swimming skills; and willingness and capability to give informed consent.	The OT program consisted of two sessions per week, each session lasting about 90 min, and included initial activation of daily living skills (mobility, dressing, grooming etc.), light warm-up, before group activities/tasks (e.g. exercising, stretching etc. in water), then relaxation; group feedback, and post-intervention activation of daily living skills.	Significant changes between groups at post intervention assessments were found in behavior problems, impairment, symptoms, social problems, and mental health.	The 12-item Spanish version of the Health of the Nation Outcome Scales (HONOS), he 36-Item Short Form Health Survey questionnaire (SF-36), Spanish version of the Basic Everyday Living Skills (BELS)	Level 3 Small sample size No blinding of staff or participants
Gunnarson AB et al (2022) Sweden	To investigate the longitudinal outcomes of the Tree Theme Method® compared with	A longitudinal study with a 3- and 12-month follow-up in a randomised	121 Participants between 18 and 65, with anxiety or depression and	Life story telling, reflective dialogue with the occupational therapist, relaxation,	Both groups improved significantly from 3 months to 12 months follow up, but there were no	Canadian Occupational Performance Measurement (COPM), Satisfaction with	Level 2

	care as usual, provided by occupational therapists, on everyday activities, symptoms, psychological and health-related aspects.	controlled trial (RCT)	problems with everyday life, recruited from primary health unit centers, and outpatient mental health care units	painting trees representing different periods in the participant lives.	significant, longitudinal differences were found between groups in any of the everyday activities, psychological or health related variables.	Daily Occupations (SDO), Occupational Balance Questionnaire (OBQ), Client Satisfaction Questionnaire (CSQ), Symptom Checklist-90-R (SCL-90-R), Montgomery-Åsberg Depression Rating Scale (MADRS-S), Hospital Anxiety and Depression Scale (HADS), Sense of Coherence Scale (SOC), Manchester Short Assessment of quality of life (MANSA), Helping Alliance questionnaire (HAq-II)	

Table 2: An updated overview of original studies investigating the effectiveness of occupational therapy interventions in mental health between 2003 and 2022.