

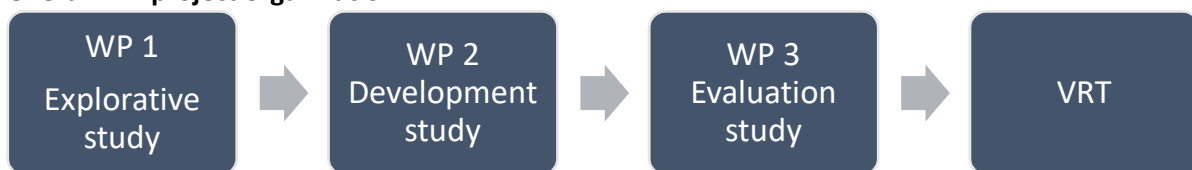
Research Protocol

“Complex socio-emotional learning in VR-based simulation training among persons with mental health and/or substance use disorders”

1. Introduction

This Ph.D. study is a part of a larger project called «Virtual Reality (VR) as a facilitator for participation in society among persons with mental health/substance use disorders» in which aims to explore, develop and evaluate a VR-based paradigm that facilitates social participation and promotes social recovery of individuals with mental health and/or substance use disorders (MHD/SUD). The overall project comprises three work packages: an exploration study, a development study, and an evaluation study. This Ph.D. study will make up work package 1.

Overall VR- project organization



2. Hypothesis, aims and objectives

The primary aim of this study (WP1) is to explore facilitators and barriers for participation in society among person with MHD/SUD, and to provide an understanding of mechanisms of social participation and social cohesion among persons with MHD/ SUD that may be affected by VR-based interventions. Finally, we will derive a socio-emotional learning domain to facilitate key interpersonal and social processes among persons with MHD/SUD in VR-based interventions. To achieve the purpose of this study we will explore facilitators and barriers for social participation as experienced as by individuals with MHD/SUD and identify key interpersonal and social processes suitable to be addressed by tailored VR based interventions.

A key factor in the utilization of VR-based learning is to target the simulation scenarios and learning mechanisms toward specific learning objectives, situations and circumstances to promote real life value of the VR experiences [5-9]. Facilitators and barriers of participation in society among persons with MHD/SUD is a topic of severe complexity. In addition, VR-based learning interventions carry a substantial learning complexity with a vast variety of learning mechanisms affecting the learning outcome of the simulations [1-4]. In computer-simulated learning environments, all the significant learning mechanisms must be created artificially. Thus, we need to provide a comprehensive understanding of both social participation mechanisms and learning prerequisites among the target group in the exploratory study (WP1) for the research group in the development study (WP2) to be able to tailor the VR-paradigm to the user's needs and preferences. Based on the service user's needs, preferences and wishes, we will determine specific learning goals needed to gain necessary skills, abilities, attitudes, and knowledge to participate fully in economic, social and cultural life in the society in which they live.

Moreover, we will explore the didactical aspects of how we can create tailored learning experiences that facilitates the achievement of the service user's (persons with MHD/SUD) desired learning objectives. [1, 2, 6]. The didactical approach to the VR-intervention development is crucial for the utility value of VR-based interventions in real life. The theoretical foundation of adult learning is primarily based on healthy and well-functioning adults. However, the combination of mental health

disorders, childhood trauma experiences, different kinds of acute and sustained substance use effects, long-term substance use consequences and different kinds of withdrawal effects often found among people with concurrent MHD/SUD both enhances dissocial behaviours and paralyze inhibitory behavioural regulation that for many leads to substantial social impairment [10-19].

Thus, we must anticipate that we not only need to study *what* the persons in our target group need to learn in order to increase their social skills mastery, but that it will be equally important to study *how* our respondents learn, in order to create an effective learning paradigm that will provide real life value for the participants.

To our knowledge, the interpersonal determinants and prerequisites of adults with MHD/SHD have not been studied in this kind of context.

The secondary aims of the study are:

1. To explore key interpersonal and social processes of social inclusion and social exclusion among persons with mental health and/or substance use disorders from the service provider's perspective.
2. To derive a socio-emotional learning domain for facilitating participation in society among persons with mental health and/or substance use disorders
3. To explore the application of VR in complex socio- emotional learning domain for facilitating participation in society among persons with mental health and/or substance use disorders.

The following research questions will be addressed:

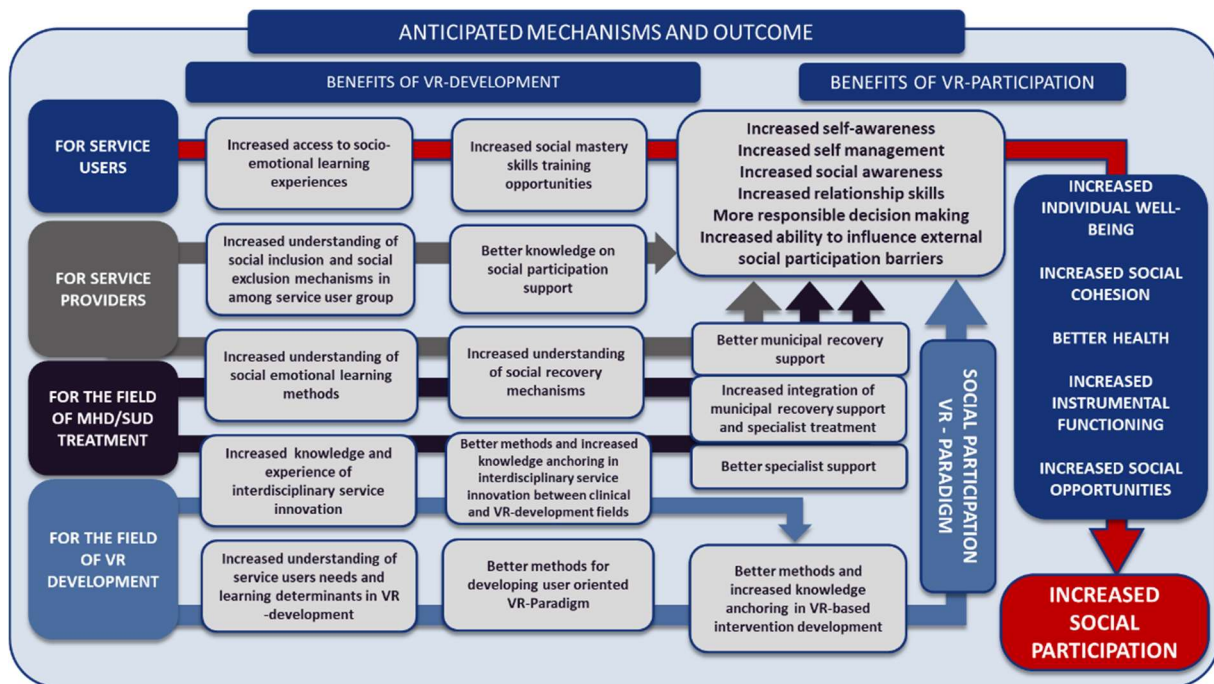
1	What is the significance of interpersonal, social, and circumstantial barriers of social cohesion and social participation among persons with concurrent MHD/SUD?
2	What is the significance of social inclusion for individual well - being and instrumental functioning among persons with MHD/SUD?
3	What are the most suppressing social and circumstantial barriers for social participation among persons with MHD/SUD from municipal service provider's point of view?
4	What is the best way to facilitate the necessary skills, abilities, attitudes and knowledge to participate fully in economic, social and cultural life and to enjoy a standard of living and wellbeing among persons with MHD/SUD and substantial social impairment in VR-based learning experiences?
5	What is the best way to efficiently applicate VR based learning for complex social learning in terms of real-life value for the service users?

3. *Project justification*

VR development has so far either been commercially driven or aimed at health professional's skills training. This study will focus on the exploration of the service user's needs, wishes, preferences and terms for learning and form a knowledge foundation to tailor the VR-paradigm to the learning determinants and learning prerequisites among the MHD/ SUD service users. This study fills the research gap between real-life and health technology, in this case virtual reality (VR), that may enhance the social participation and quality of life of one of the most vulnerable service user groups.

Our study has desired societal impacts for several stakeholders:

Anticipated mechanisms and outcome



We anticipate both direct real-life user value from VR-participation, and additionally increased knowledge about the socio-emotional disabilities among person with MHD/SUD. In turn, we may increase the understanding of these peoples struggles with social impairments and lack of social support. Ultimately, this study also will contribute to a better facilitation of external social participation mechanisms and social opportunities.

4. Research participants, organization and collaborations

The initiative for this research project comes from the Norwegian Advisory Unit on Concurrent Substance Abuse and Mental Health Disorders (NKROP), which has established a research group in cooperation with Innlandet Hospital Trust, Hamar municipality, the user organization RIO and VID Specialized University.

Lars Lien, senior researcher at NKROP, will take on the role as project manager.

NKROP has been collaborating previously with the partners of this project: RIO was involved in the development of the National guideline for patients with concurrent mental health and addiction disorders, which was led by NKROP. In addition, the municipality Hamar cooperated with NKROP on several recovery projects and recently on a project on the impact of COVID-19 on persons with MHD/SUD. In this study, we cooperate with excellent international partners from: Yale School of Medicine (USA), the University of Regensburg (Germany), Hamburg Centre for Health Economics (Germany), University of Stockholm (Sweden) and King's College, London (UK).

Service User involvement

Our study approach provides for service user involvement from the design of the study to dissemination of the results. The Norwegian service user board, established by NKROP in 2012, has approved the final study protocol. Service users from our collaboration partner RIO (service user organization) act as multipliers; they will disseminate the project into their peer communities where we will also recruit the 20 participants in WP2 (the development study). Service users and peers with training in research will be invited to co-author articles, take part in conferences, and plan community meetings based on the project results.

The Research Group comprises

Name	Affiliation	Core Competencies	Task
Lars Lien	Professor HINN, UIO, UIT. Former director of NKROP	Project management Social psychology	Project leader
Marja Leonhardt	Lecturer at VID specialized University. Post.doc NKROP	Epidemiology Mixed methods	Project Leader Main Supervisor
Bente Røstad	RIO	Peer support research	Project partner
Håvard Vibeto	Associate Professor HINN	VR-development	Project Partner
Phillip Lindner	Psychologist VR-researcher Karolinska Institutet	Clinical VR-development	Project Partner
Anita Østheim	Head of Centre for Life Mastery Hamar municipality	Cognitive therapy	Project partner
Torgeir Sørensen	Associate professor at VID specialized University		Co-supervisor
Jan Aasen	Ph.D. Candidate at NKROP		Recruitment, interviews, analysis, & publications
Kari Galaaen	Psychologist Specialist Hamar Municipality Lecturer VID		Researcher Study 2 Recruitment, interviews, analysis, & publications
Morten Brodahl	Peer support worker NKROP, leader service user board	Peer support research	Advisory board member, Recruitment WP1-2, Observer focus groups WP1
Fredrik Nilssen	Regional head of RIO		
Rune Lundquist	Sagatun Brukerstyrt Senter, Hamar		
Michael Rowe	Prof of Psychiatry, Yale School of Medicine, USA	Research on citizenship as an applied theoretical framework for social inclusion with MHD	Members of the advisory board
Morris Bell	Prof. of Psychiatry, Yale School of Medicine, USA	VR job interview training program, clinical trials	
Lucia Valmaggia	Prof. of Psychology at King's College London, UK	Clinical psychology and digital mental health, RCT with VRT	
Valerie DeMarinis	Prof. public MH & psychology of religion at Inland Hospital Trust & Uppsala University, SI	Cultural psychology, intervention and prevention program	

5. Subject recruitment

Target Group

The target group of this project are both male and female adults diagnosed with mental health and substance use disorders (MHD/SUD), and substantial social impairment in the last two years

Participants

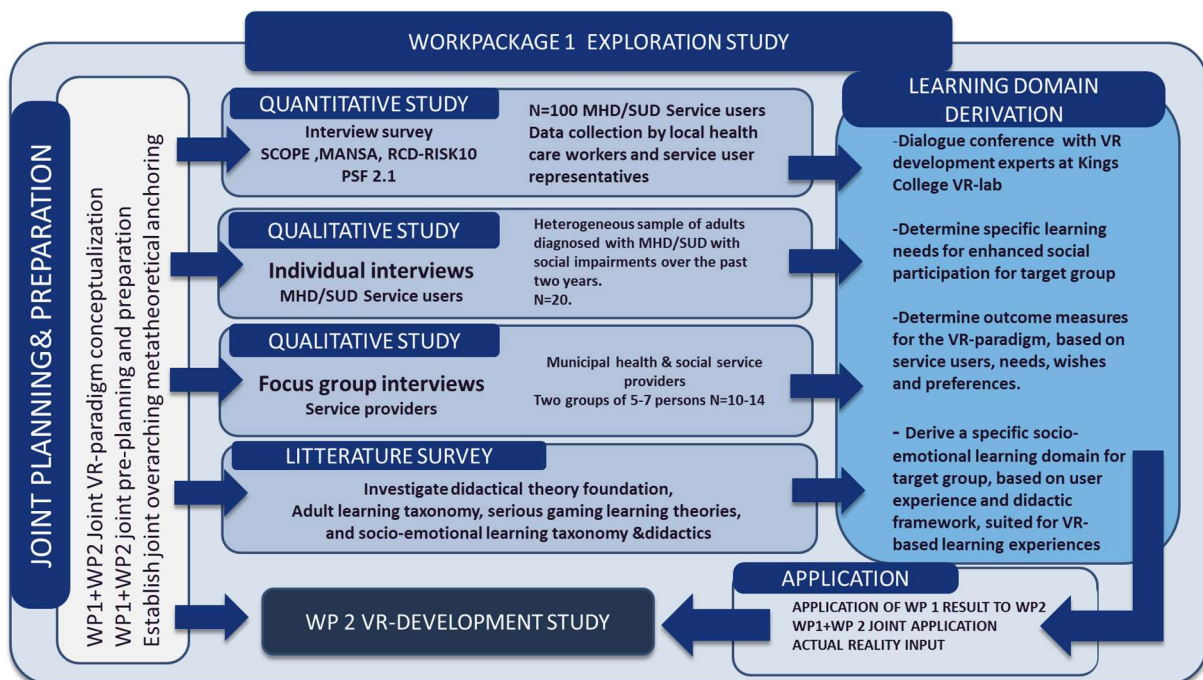
We will recruit the participants of this study among adults diagnosed with MHD/SUD, receiving local services in our collaborating municipality (Hamar). Inclusion criteria are being above 18 years of age and receiving services in the municipality of Hamar due to mental health and /or addiction problems. Exclusion criteria will be visual and hearing impairment, neurological disorders, and mental retardation [score ≤ 70 on the Test of Intelligence]. Participant recruitment will be conducted by, and in collaboration with the peer support researchers at NKROP, RIO, Sagatun Brukerstyrt Senter and Hamar commune.

6. *Project arrangements, method selection and analysis*

Studies and data collection

To facilitate a comprehensive understanding of the factors that contribute to both social participation and real-life learning outcome from VR-based learning for WP 2, we need to collect a wide variety of data and a conduct a variety of analysis. Therefore, we will organize our work package in three empirical studies and one literature survey. Each of these studies will generate data for publication. Finally, we will synthesize all four studies together in one compound socio-emotional learning domain, tailored to the MHD/SUD service user's learning prerequisites in VR-based learning disseminations. The separate studies will be differently analyzed, both by quantitative and qualitative analysis. The reason for this mixing of methods is to utilize the advantages from different methods and use the results from the different data sets to explain each other's patterns in the analysis. To achieve the proper understanding of data during the analysis we will need to consecutively exchange preliminary findings between the studies. In addition, WP1 and WP2 needs to be coordinated in a joint planning and preparation process. WP1 is therefore carefully orchestrated:

Work package 1 orchestration



Study descriptions

Study 1	<i>Exploration of key interpersonal and social barriers among persons with mental health and / or substance use disorders from the users perspective</i> Quantitative approach
Research Questions	<ol style="list-style-type: none"> 1. What is the significance of interpersonal, social, and circumstantial barriers of social cohesion and social participation among persons with concurrent MHD/SUD? 2. What is the significance of social inclusion for individual well - being and instrumental functioning among persons with MHD/SUD?
Method	In this study we will conduct a quantitative interview survey, as this method is suitable for a vulnerable target group such as persons with MHD/SUD and promises a higher commitment and validity of data as an interviewer guides the participants through the assessment tools[20]
Data Collection	Health and social workers from our collaboration partner (Hamar municipality) and the members of the research group will conduct the interviews on an individual basis – either in person or via telephone. Data collection will be managed by designated and trained local health care workers in cooperation with service user representatives who also will take part as peer researchers.
Subject Recruitment	For this study, we will recruit 100 persons receiving services in Hamar, Stange, Løten, Ringsaker, Elverum and/ or Oslo due to their MHD/SUD. N=100
Assessment Tools and Analysis	Social and Community Opportunities Profile (SCOPE) measuring social participation [21], MANSA quality of life [22], R-CD-Risc10 resilience[23], and Practical & social functioning (PSF) version 2.1. The SCOPE questionnaire is being translated and culturally adapted to the Norwegian context by the Norwegian Advisory Unit for Concurrent MHD and SUD (NKROP). The instruments QoL-MANSA , R-CD-Risc10, and PSF 2.1 have all been validated in a Norwegian context [24] The results will be analyzed by using linear and multiple regression models

Study 2	<i>Exploration of key interpersonal and social barriers among persons with mental health and / or substance use disorders from the users perspective</i> Qualitative approach
Research Questions	<ol style="list-style-type: none"> 1. What is the significance of interpersonal, social, and circumstantial barriers of social cohesion and social participation among persons with concurrent MHD/SUD? 2. What is the significance of social inclusion for individual well - being and instrumental functioning among persons with MHD/SUD?
Method	We will conduct qualitative individual interviews applying the method of “user interviews user” [25].
Data Collection	Members of our collaborating service user organization RIO, and peer support worker at NKROP will perform the interviews. Data collection will be managed by designated and trained local health care workers in cooperation with service user representatives who also will take part as peer researchers.
Subject Recruitment	We will use a criterion-based sampling procedure in the recruitment of a heterogeneous sample of max. 20 persons (adults diagnosed with MHD/SUD with substantial impairment in the last two years), receiving local services in our collaborating municipalities.
Assessment Tools and Analysis	Transcripts from the individual interviews will be analyzed using Brown and Clark’s thematic analysis[26]. The steps include coding, categorizing, and meaning -making, moving from the manifest to the latent content of the text.

Study 3	<i>Exploration of key interpersonal and social barriers among persons with mental health and / or substance use disorders from municipal health service providers point of view, qualitative approach</i>
Research Questions	3. What are the most prominent barriers for social participation among persons with MHD/SUD from municipal service provider's point of view?
Method	Qualitative focus group interviews.
Data Collection	For RQ4, we will conduct two focus group interviews (each group ca. 5-7 persons)
Subject Recruitment	Service providers, recruited from Hamar municipality (N total = ca. 10-14 persons)
Analysis	Transcripts from the individual interviews will be analyzed using Brown and Clark's thematic analysis[26]. Data collection and analysis will be conducted by project partner in Hamar municipality

Study 4	Explore the application of VR-based learning in complex socio-emotional learning among persons with MHD/SUD,
Research Questions	<p>4. What is the best way to facilitate the necessary skills, abilities, attitudes and knowledge to participate fully in economic, social and cultural life and to enjoy a standard of living and wellbeing among persons with MHD/SUD in VR-based learning experiences?</p> <p>5. What is the best way to efficiently applicate VR based learning for complex social learning in terms of real-life value for the service users?</p>
Method	The main purpose of research questions 4 and 5 is to bridge the gap between the understanding of barriers for social participation among individuals with MHD/SUD and VR-intervention development. In this study we will also determine which learning goals will be best suited for specifically tailored VR- based learning, and which didactical requirements will be best suited for the facilitation of the determined learning goals. To answer these research questions, we will perform a literature survey on adult learning theories and adult learning taxonomy and focus group interviews with VR- engineering experts at the Virtual Reality Lab NIHR/Wellcome Trust King's College Clinical Research Facility in London. These focus group interviews will be arranged as dialogue conferences where the preliminary analysis of study 1-3, and VR application will be discussed.
Data Collection	Literature survey Focus group interview
Subject Recruitment	We will recruit VR- developers with expert knowledge on development of VR paradigms for social learning. N=5
Analysis	We will audiotape the dialogue conference and the transcriptions will put together into one compound text material that will be analyzed using Lindwalls (2010) five-step hermeneutical text interpretation. This analyzing process includes text integration, fusion of pre-understandings, text questioning, categorization of themes and sub-themes, and summary of the new understandings. This analysis process can be seen as a dialogue between the scientific researcher's theoretical pre-understanding and the co-researches empirical pre-understandings in the text. It is through this dialogue the theoretical and empirical pre-understandings merge into new knowledge[28].

7. *Plan for implementation*

Our developed and tested VR-paradigm will be implementation ready if the evaluation shows sufficient learning outcome. The implementation may be conducted through NKROP, in which provides the training of the Norwegian FACT-Teams (Flexibel Assertive Community Treatment). These FACT teams provide assertive outreach treatment for persons with concurrent mental health and substance abuse disorders and specialize in taking the services directly to the patients in their own home environment and their local community. In addition, this study will provide knowledge on what hinders or promotes social inclusion within their recovery process. This understanding will facilitate not only the development of tailored recovery measures, but also measures to prevent persons with MHD/SUD being marginalized and falling out of society. Further, applying the newly culturally adapted assessment tool SCOPE in a large study to measure social inclusion will be of great additional value, not only in public health but also in social science research in Norway, as it will be the first tool to measure social inclusion of persons with MHD/SUD. The development of a prototype of VRT to enhance social inclusion will have a far-reaching impact for several disadvantaged groups, which may face difficulties participating in society; our “welfare technology” will easily be adaptable for other groups than those with MHD/SUD. Our research will provide a blueprint for how a VR experience may be designed. Although developed and applied in the welfare sector, it may encourage use in other sectors as well.

8. *Funding and interests*

This project is funded by the Research Council of Norway (projectnr 326773) and is administrated by the research department at Innlandet Hospital Trust, The National Advisory Board of Concurrent Mental Health and Substance Abuse Disorders.

9. *Ethical Considerations*

The project will be conducted in line with the Norwegian guidelines for medical and health research as well as the Declaration of Helsinki. Consent to participate in the research project will be collected from service users by the recruiting service. All participants will be informed about the benefits and risks of participating in the project and give written consent to participate. The Ph.D. fellow will process collected data. Data will be stored in the hospital's approved research server in unidentified form. The link between the data files and the person identity will be stored separately in locked cabinet. Participation can be withdrawn at any time without giving a reason.

10. *Safety Considerations*

This study will focus on the mechanisms and significance of social participation and social cohesion for persons with mental health and/or substance abuse disorders. We will conduct individual interview survey and individual interviews among the service user participants, who is considered a vulnerable group. Peer service users and/ or trained service providers will conduct the interviews. We consider this to entail a low risk, in which to a very small extend will constitute any safety issues for the participants. Nevertheless, professional peer research workers will supervise the interviews. In addition, we will also conduct focus group interviews, where professional service providers will be participants. We do not consider this group of participants as a vulnerable group, and see no safety issues regarding the focus group interviews. There will not be conducted any VR-based simulation testing in this study. However, the results of this study are intended to be utilized in the further development of a VR-based paradigm, in which makes it necessary for us to take safety considerations of VR simulation into account from the very beginning of the VR-development process.

All VR -based simulations creates an altered sense of reality. However, most individuals with intact mental functioning can distinguish between virtual and real environments and efficiently detect errors or distortions. Persons with already impaired senses of reality may be at high risk for further distortion of their reality testing. Persons with higher levels of dissociative symptoms thou far from clinical levels of dissociation has shown increased dissociative symptoms and decreased objective reality after exposure to VR for 20 minutes. This suggests that dissociation, depersonalization and derealization may be triggered through discontinuity in perceptual environments, and that it is possible that prolonged periods of discontinuity in objective perception may have harmful effects in vulnerable individuals

11. Schedule

Year		2021	2022				2023				2024			
Task	Quarter	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Study 1														
1.1	Study planning and preparing													
1.2	Cultural adaption of SCOPE													
1.3	Recruitment and training of peer researchers													
1.4	Data collection: User Interview survey													
1.5	Data Analysis													
1.6	Writing up article 1													
Study 2														
2.1	Planning and preparing													
2.2	Recruitment													
2.3	Data collection: Focus groups													
2.4	Data analysis													
2.5	Writing up article 2													
Study 3														
3.1	Study planning an preparing													
3.2	Recruitment													
3.3	Data Collection													
3.4	Data Analysis													
3.5	Writing up article 3													
Study 4														
4.1	Planning and preparing													
4.2	Litterature Survey													
4.3	Dialouge Conference King's College London UK.													
4.4	Data analysis													
4.5	writing up article 4													
Cross study tasks														
1	Study protocol revision													
2	Research Group meeting													
3	PHD Courses													
4	Writing up meta report and synopsis													
5	Defense													

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