

**Individualized Intersectoral Activity-based Rehabilitation Programme
for elderly with Hip Fractures (IIARP-HF)**

**Intersectoral rehabilitation for elderly with a hip fracture
based on daily activities**

Application regarding study I and II

**Development and evaluating an intersectoral rehabilitation focusing on daily
activities for elderly with a hip fracture**

Study III (funding received elsewhere)

The effect of an individualized intersectoral activity-based rehabilitation program for
elderly with hip fracture

An Intersectoral randomized controlled trial

PREFACE	3
1. INTRODUCTION AND RATIONALE.....	4
2. OVERALL AIM, RESEARCH QUESTIONS AND HYPOTHESIS.....	5
2.1. Overall aim	5
2.2. Overall research questions.....	5
2.3. Study I: Objectives and Hypothesis.....	6
2.4. Study II: Objectives and Hypothesis	6
2.5. Study III: Objectives and Hypothesis.....	6
3. STUDY DESIGN, MATERIAL AND METHODS.....	7
3.1. Study I	7
3.1.1. Inclusion and exclusion criteria for elderly with HF and HCP.....	8
3.1.2. Recruitment study I	9
3.1.3. Intervention study I.....	9
3.2. Study II	10
3.2.1. Inclusion and exclusion criteria for elderly with HF	11
3.2.2. Recruitment study II	11
3.2.3. Intervention study II	12
4. THE FEASIBILITY OF THE PROJECT.....	12
5. INTERSECTORAL COLLABORATION	13
6. ETHICAL CONSIDERATION.....	13
7. RELEVANCE AND PERSPECTIVES.....	14
8. DESSERMINATION OF RESEARCH	14
9. REFERENCES	16

PREFACE

The municipalities Herlev and Gentofte and the University Hospital Herlev and Gentofte initiated this project with the overall aim of improving the intersectoral rehabilitation for elderly with hip fracture. This is the first step in developing, evaluating and implementing an intersectoral rehabilitation program for elderly with hip fracture.

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1. INTRODUCTION AND RATIONALE

Hip fractures (HF) are the most serious fall-related cause of morbidity in elderly, with a high number of hospitalizations every year, often associated with a poor physical function and inability to perform Activities of Daily Living (ADL) (1,2). In Denmark, in 2016 6.789 elderly with HF were hospitalised (3). This number is expected to increase, due to the increase in the number of elderly (1-2). Despite positive surgical outcomes, only about half of the patients are able to return to home after HF and just one-third regain their pre-fracture level of physical functioning and ADL ability (4,5). After HF, the loss of independence in ADL often persists beyond three months after surgery (6). This increases the risk of social isolation, depression etc. (7-12). Therefore, rehabilitation intervention aimed at reducing the degree of dependence in ADL is crucial in elderly with HF.

Reablement has become an emerging approach in rehabilitation, focusing on client centred goals in relation to ADL. Reablement is defined as; *'services for people with poor physical or mental health to help them accommodate their illness by learning or re-learning the skills necessary for daily living'* (13). With this approach, health care professionals (HCP) employed at the hospitals and the rehabilitation centres in the municipalities work together with elderly to achieve independence in Personal Activities of Daily Living, e.g. undertake personal hygiene, eating/drinking, move around indoors (PADL) and Instrumental Activities of Daily Living, e.g. domestic work, gardening and shopping IADL (14). However, reviews of the effectiveness of this approach have shown inconsistent results (15). Nevertheless, the guidelines from the National Institute for Health and Care Excellence (NICE) (16) and Danish Clinical Guidelines regarding the management of hip fracture (17), recommend a multidisciplinary rehabilitation programme after initial medical treatment.

Rehabilitative efforts in Denmark often include the multidisciplinary team with physiotherapists, occupational therapists, doctors, nurses and health care assistants (18). According to the guidelines, rehabilitation should begin in the hospital during the acute phase, then following discharge at the municipality's rehabilitation centre, securing a seamless transition from one sector to the other. In some studies, the results shows that preventive home-visits in regards to adapting the home environment after discharge, increased safety, reduce the risk of falling and an increase independence in ADL (12,19,20).

Rehabilitation Course Descriptions for patients with HF are initiated during hospital stay. However, transfer of knowledge and coordination across the health care system does not always meet vulnerable citizens' needs (21) and Sundhedsaftalen 2015-2018 deems it necessary to ensure and establish structures for adequate healthcare across sectors (22).

In summary, there is a need to develop and evaluate an individualized intersectoral activity-based rehabilitation programme for elderly with HF ≥ 65 years (IIARP-HF). By developing and evaluating such a rehabilitation programme, we will be able to improve the effects of rehabilitation for the elderly with HF. Therefore the present study aim to develop and evaluate an IIARP-HF for elderly with HF based on the first step in the Medical Research Council's (MRC) framework for developing and evaluating complex interventions (23) (Fig. I and II).

2. OVERALL AIM, RESEARCH QUESTIONS AND HYPOTHESIS

2.1. Overall aim

The aim is to develop and evaluate an IIARP-HF focusing on individual customized rehabilitation regarding PADL and IADL enabling elderly with HF to safely and independently perform ADL, and thereby enhance their health related quality of life.

2.2. Overall research questions

What are the expectations, needs and experiences of the elderly with HF, their relatives and the HCP to an IIARP-HF? (Study I)

What is the feasibility of the IIARP-HF, and which factors have to be taken into account, when evaluating and adapting the programme for implementation? (Study II)

What is the effect, measured on the quality of the ADL performance and independence and health-related life-quality of an IIARP-HF for elderly with HF? (Study III)

This application applies for the initiation and completion of study I and II

2.3. Study I: Objectives and Hypothesis

Objectives: To developing an IIARP-HF for the elderly with HF. This investigation is structured as a qualitative action research study using Research circles (RC) (24,25). Through a series of RC, this study will develop a programme by using a client-centred and dialogue-based communication, collaboration and exchange of information and knowledge about rehabilitation of elderly with HF across sectors by the HCP in a close collaboration with the elderly with HF.

Hypothesis: This study is based on the assumption that an IIARP-HF developed in collaboration with users and HCP will show the largest potential for implementation and patient satisfaction.

2.4. Study II: Objectives and Hypothesis

Objectives: To evaluate the feasibility of an IIARP-HF for elderly with HF. This study will take the adherence, technical and practical circumstances into account when evaluating the feasibility of the programme, developed in study I.

Hypothesis: By testing the feasibility of an IIARP-HF for elderly with HF and the usefulness of the selected measurement tools, we will be able to evaluate and adjust the IIARP-HF before conducting a Randomized controlled trial (RCT).

2.5. Study III: Objectives and Hypothesis

Objectives: To evaluate the effect of an IIARP for elderly with HF on the quality and independence in ADL performance, measured with AMPS and health-related quality of life measures.

Hypothesis: The IIARP-HF will increase the quality and independence in ADL performance, measured with AMPS and health-related quality of life measures.



Figure I. Studiedesign

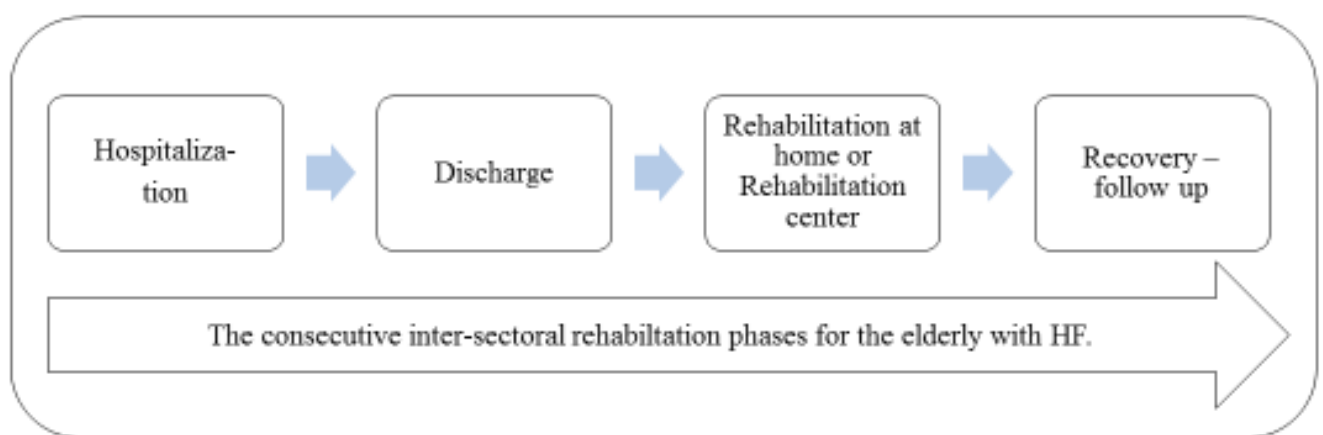


Figure II: Rehabilitation phases for the elderly with HF.

3. STUDY DESIGN, MATERIAL AND METHODS

The studies are designed according to the MRC's guidelines for Developing and Evaluating Complex Interventions (23).

3.1. Study I

This qualitative study has a participatory design and will be conducted in two RC (24,25), in which expectations, needs and experiences of the elderly with HF, their relatives and the HCP in charge of rehabilitation, to an IIARP-HF are in focus.

RC is a collaborative research approach to ensure and establish structures for participation by all stakeholders in different aspects of the research process. The approach allows HCP and health care users to take ownership of the research and critically reflect during this iterative process. This approach enables a

deeper understanding of the local context, as well as the creation of a more accurate framework for assessing and adapting “best practices” to meet the needs of elderly with HF. The use of RC, will assure that the elderly with HF shares information, experiences and needs from their recent rehabilitation, and from HCP during their involvement in rehabilitation of elderly with HF. Two separate RC will be used to gather data for this study. The first RC will consist of elderly with recent HF rehabilitation experience and their relatives; the second RC will consist of HCP.

3.1.1. Inclusion and exclusion criteria for elderly with HF and HCP

Inclusion criteria in RC – elderly with HF:

- Age 65 years or older
- Recent proximal HF (S 72.0 Medial femur fracture, S 72.1, Pertrochanter femur fracture, S 72.2 Subtrochanter femur fracture)
- Living in their home prior to HF in Herlev and Gentofte municipalities
- Ability to give informed consent
- Discharged from hospital and receiving or having received rehabilitation in one municipality within the last 3 months from onset

Exclusion criteria in RC – elderly with HF:

- Not expected to be discharged to home or rehabilitation centres in the municipality
- Not able to speak and/or understand Danish
- Subjects who have prior severe physical and /or mental disabilities

Inclusion criteria in RC – HCP:

- Minimum of 2 years of experience in rehabilitation of elderly with HF in one of the included municipalities or at Herlev and Gentofte Hospital

3.1.2. Recruitment study I

First RC: Final inclusion will be accomplished after finishing their rehabilitation intervention. It will be possible to include relatives to join the RC, if they have been a part of their relative's rehabilitation, and can support the elderly.

Elderly with HF: 8 persons, 4 from each participating municipality with HF who has been hospitalized at the Orthopaedic ward T119 at Herlev and Gentofte Hospital during the spring/summer of 2017.

Individuals with HF and their relatives are invited to RC in which selected topics related to the experiences, needs and expectations of an intersectoral activity-based individually tailored rehabilitation program will be discussed in the group. The course aims for a maximum variation, e.g. age, gender, education, housing, living alone or with partner, accessibility in the home etc. Recruitment of elderly with HF and their relative's will be carried out during September 2017 in a cooperation between research assistant (AR), the project group and the HCP in the municipalities. If transportation to the meeting is needed, taxi will be provided.

Second RC: This RC will consist of six HCP (3 from each municipality) as well as by two HCP from Herlev and Gentofte Hospital. Recruitment of HCP will be done during September 2017. The RC's will be conducted in the municipality's rehabilitation centres.

3.1.3. Intervention study I

There will be four meetings in each RC. The meetings have a two-hour duration with three weeks between each meeting. The research assistant pre-prepares the overall theme for each meeting and will discuss the theme on equal terms with participants. The themes will be related to the elderly's PADL and IADL challenges during hospitalization and after discharge from hospital. At each meeting, the exchange of knowledge and experiences are digitally recorded for later transcription and analysis. At the beginning of each meeting, a conclusion from the former RC will be presented. At the fourth meeting the two RC get together to share their knowledge in order to agree on the required content in a rehabilitation programme. The discussions from meetings will be analysed consecutively and the results will be the IIARP-HF (26) (Figure III).

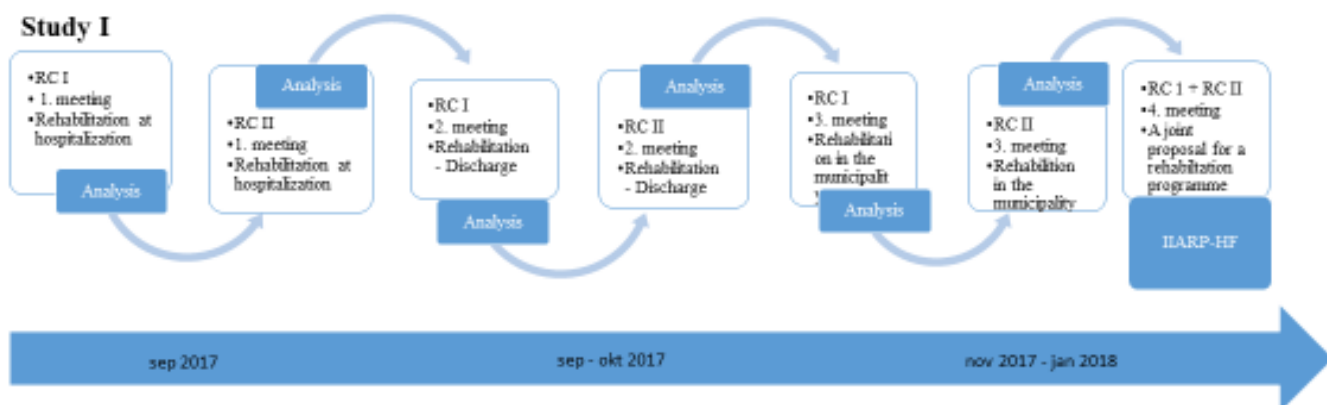


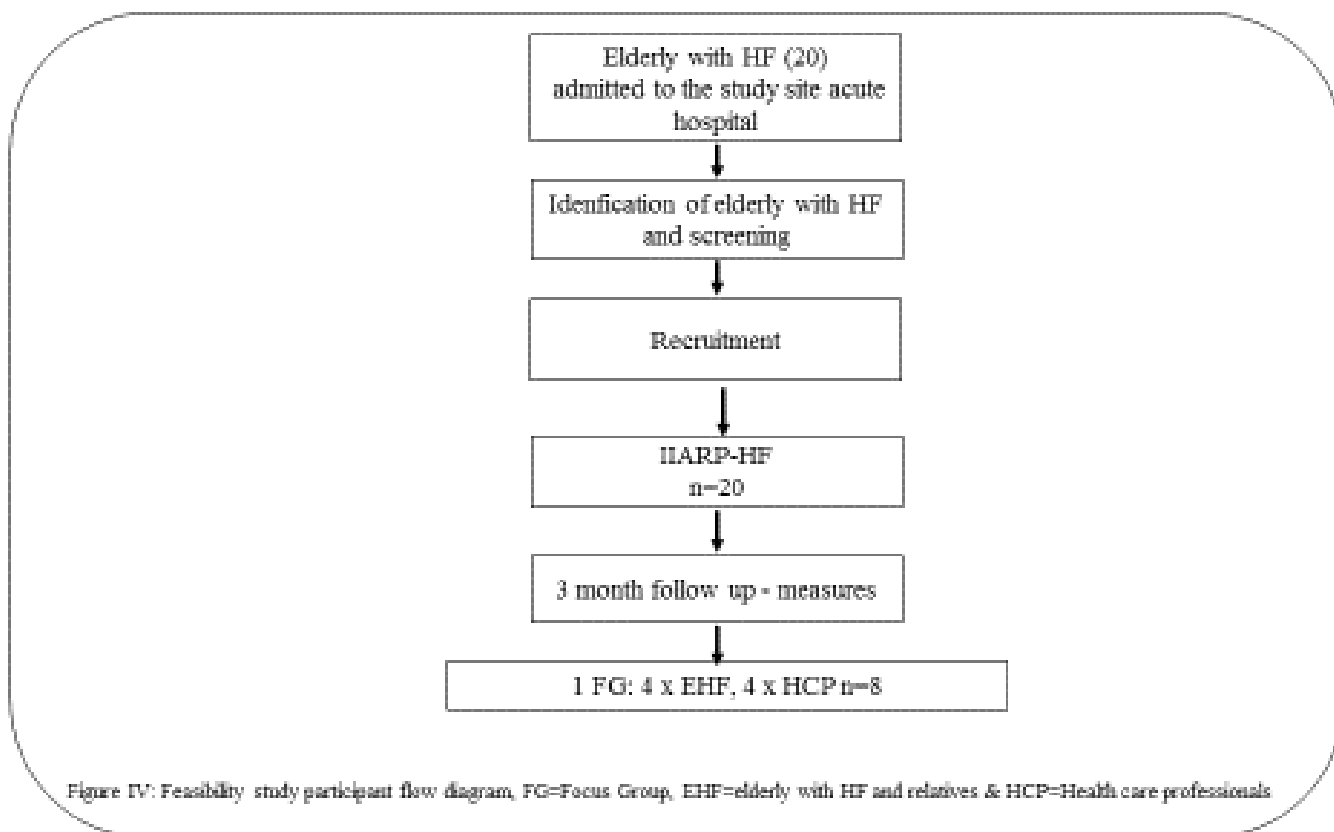
Figure III: Elderly with HF and relatives=Research circle I (RC I), Health care professionals=Research circle II (HCP II) and topics during meetings.

3.2. Study II

Study II comprises the second stage of the MRC framework for assessing complex interventions (23).

The IIARP-HF developed in study I, will be evaluated with 20 elderly with HF (Figure 4 and table I), hospitalized at the Orthopaedic Ward T119 in Herlev and Gentofte Hospital and subsequent rehabilitation in municipality.

This study will evaluate the usefulness of the IIARP-HF as a focus for the intersectoral collaboration. The acceptability and feasibility of the IIARP-HF will be assessed in a focus group interview (FG) consisting of the included elderly with HF, their relatives and HCP. In this interview, the advantages and disadvantages of the IIARP-HF will be discussed.



3.2.1. Inclusion and exclusion criteria for elderly with HF

Same inclusion and exclusion criteria as study 1.

3.2.2. Recruitment study II

Elderly admitted to Herlev and Gentofte hospital from April to October 2018 are eligible.

Primary Outcome study II: ADL ability: The Assessment of Motor and Process Skills (AMPS), which is a standardized observation-based evaluation tool to measure a persons observed quality of ADL task performance in terms of physical effort and/or fatigue, efficiency, safety and independence (27,28).

Secondary outcome study II: Functional Recovery Score (FRS) (29), Health-related quality of life: European Quality of Life Scale (EQ-5D) (30).

Other data collected in study II: Age, gender, type of fracture, waiting time for surgery, length of stay in acute hospital, marital status, type of dwelling, Comorbidity (Charlson Index), 30-days mortality, Base mobility cumulated ambulation score (CAS), physio- and occupational therapy services, level of education,

motivation for rehabilitation, main health challenge, warranted community-based assistance, inpatient and outpatient treatment since last assessment, usage of home-based services, pain score.

Activity	Timeline			
	B	D3	A3	P3
Table 1: IIARP-HF study II activity and procedures				
Eligibility screening and content for feasibility study:				
• Elderly with HF	X			
Outcome measurements for feasibility study:	X			
• Primary (AMPS, motor)	X		X	
• Secondary (FRS + EQ-5D)	X		X	
Further registration:				
• Basis mobility (CAS)	X			
• Comorbidity (Charlson Index)	X			
• 30 days mortality	X			
• Age	X			
• Gender	X			
• Waiting for surgery	X			
• Type of fracture	X			
• Type of surgery	X			
• Place of residence prior to admission	X			
• Pain score	X			
• Home services prior to admission	X			
• Number of readmission	X			
Qualitative follow up elderly with HF and HCP in FG:				
• Elderly with HF				X
• HCP				X
Recruitment and consent		X		
B=Baseline, D3=During 3 months, A3=At 3 months & P3=Post 3 month follow-up				

3.2.3. Intervention study II

The main aim of the IIARP-HF is to increase the quality of ADL performance and self-rated quality of life for the elderly with HF and thereby improve their ability to live independent at the 3-months follow up. The IIARP-HF will be tailored to the need of elderly with HF in a liaison with the HCP. The included elderly with HF will at their first post-operative day at the hospital evaluated using the AMPS (28) and a FRS (29) and EQ-5D (30). AMPS will be carried out, at admission by completed rehabilitation and at 3 months follow-up in order to clarify the elderly with HF's challenges with PADL and IADL. This is to test the feasibility of the IIARP-HF in daily practice in the hospital and in the municipalities.

4. THE FEASIBILITY OF THE PROJECT

The primary investigator Carsten B. Juhl is responsible for the overall project management and use of resources during the studies, and will in a collaboration with research assistant Alice Røpke carry out

foundation of applications, data collection, analysis, ensure recruitment, correspondence with the participants and production of scientific articles. A project coordinator from Herlev and Gentofte Hospital will be a part of the recruitment process in study II (Figure V).

In 2016 114 people were hospitalized with HF in the Orthopaedics ward; Herlev and Gentofte Hospital, from Herlev and Gentofte municipalities and it is expected that at least one out of four may be included, making it feasible that study I and study II can be performed by the end of 2018.

5. INTERSECTORAL COLLABORATION

This project was developed in a collaboration between Herlev and Gentofte Hospital, the Intersectoral Research Unit (Tværsektoriel Forskningsenhed), Development and Research and Gentofte and Herlev municipalities. A project team consisting of representatives from the participating municipalities and the hospital will be established along with an intersectoral advisory board comprising representatives from the Department of Occupational Therapy, Physiotherapy and Department of Orthopaedic Ward, at Herlev and Gentofte Hospital; the Intersectoral Research Unit (Tværsektoriel Forskningsenhed); and Gentofte and Herlev municipalities. The primary investigator, together with the advisory board, will have the overall responsibility for compliance with the schedule, budget and decisions about economy and adjustments of the IIARP-HF. The intersectoral advisory board must approve the IIARP-HF, and is responsible for anchoring the program in the municipalities and at the hospital. The execution of study I and II will be organised and performed by the HCP employed at the hospital and in the municipalities, and the primary investigator and research assistant.

6. ETHICAL CONSIDERATION

Eligible elderly with HF will be informed orally and in writing about the study's purpose, process and potential risks and benefits of participation and that they may withdraw from study 1 and 2 at any time without any consequences for their future rehabilitation or other social and health services (31).

In addition, the leaflets '*Før du beslutter dig*' and '*Rettigheder som forsøgsperson i et sundhedsvidenskabeligt forskningsprojekt*' will be distributed before signing an informed consent form. The protocol will be approved by the Regional Scientific Committee (Videnskabsetiske Komiteer for Region Hovedstaden). The Danish Data Protection Agency (Datatilsynet) will be requested for authorization for storage of data.

7. RELEVANCE AND PERSPECTIVES

The project will contribute to a more coherent rehabilitation for elderly with HF, and increase their independence in performing PADL and IADL.

8. DETERMINATION OF RESEARCH

The results will be presented nationally and internationally at conferences and published in peer-reviewed scientific journals. At any publication the fund's contribution will be noted.

Activity	Initials	2017				2018				2019				2020			
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
STUDY I																	
Positive agreement and collaboration between MP&H	CBL, AR																
Submit application Tværspulje	CBJ, AR																
Preparing the research circles	AR																
Recruitment of E&HP	AR, KL																
Signing informed content	AR, HCP																
Conducting research circles	AR, E&R, HCP, H																
First publication initiated	AR, KL																
Analysing data - development of IIARP-HF	CBL, AR																
STUDY II																	
Feasibility study initiated	CBJ, AR, E&R, KL, HCP, H																
Screening	AR, KL, E&R, HCP, H																
Signing informed consent	AR, KL, HCP, H																
Recruitment to focus group with E&R & HCP	AR																
Evaluation of feasibility	CBJ, AR, MP, H																
Focus group with E&R & HCP	AR																
Second publication	CBJ, AR																
Report/Publication	CBJ, AR																
CBJ=Carsten B Juhl, AR=Alice Røpke, KL=Karina Lund, HCP=Health Care Professionals, E&R=Elderly with HF and their relatives, MP=Municipalities, H=Hospital																	

Figure V: Flow-chart: Procedures and timelines for study I & II

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