

Integrated Psychosocial Care in Intensive Care (IPS-Pilot): Study Protocol of the Systematic, Multi-Method Development of a Complex Intervention (Phase A)

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Abstract

Background: There is a high and co-dependent strain on health care professionals (HCPs), patients and their relatives in intensive care units (ICUs), leading to long-term mental, physical and occupational consequences. To this date, there is no systematic intervention to address this increasing problem.

Objective: The aim of the IPS-Pilot project is the development (phase A) and pilot testing (phase B) of an integrated and complex psychosocial care intervention for HCPs, patients, and their relatives in ICUs. This study protocol focuses on phase A. A protocol for phase B will be published separately.

Methods: A structured, multi-method approach was used to gather evidence on the needs, expected benefits and necessary conditions for implementation from the above target groups. These methods included: 1) a scoping umbrella review conducted by two researchers who independently screened and selected reviews and meta-analyses conducted in the field of needs and demands in the ICU setting according to the Levac framework, 2) web-based and face-to-face interviews and focus group discussions, coded by two researchers independently and analyzed with qualitative content analysis by Kuckartz, with the identified categories and codes then being quantified by 3) an online survey with former ICU patients, their relatives, HCPs working in ICUs and the general population. Synthesized results, complemented with the theories of Psychosocial Safety Climate (PSC) and Conservation of Resources (COR) as well as online and face-to-face stakeholder workshops, were used for intervention development which was based on the Intervention Mapping framework.

Results: Through the four substudies, we aim to gain insight into the psychosocial needs of the above-mentioned target groups. We performed intermediate analyses to develop a model of the problem as well as a model of how these needs can be effectively addressed through a psychosocial intervention involving the integration of a clinically trained psychologist into the HCP team. Data collection and analysis for the intervention development was completed by June 2024 (Substudy 1: N=104 included articles, Substudy 2: N=22 interviews and N=18 participants in focus groups, Substudy 3: N=237 participants in the survey, Substudy 4: N=11, N=15 and N=20 participants in three consecutive workshops), with further analyses still being conducted that go beyond the intervention development. The results of the substudies as well as the final, needs-based intervention design will be published separately. These findings set the base for the feasibility study (phase B) from July 2024 to July 2025 in which the

intervention will be implemented in randomly selected ICU wards and evaluated in terms of feasibility.

Conclusions: Phase B will assess the feasibility of the IPS intervention. These findings will then be incorporated into our intervention design and provide the basis for a future randomized controlled trial of its efficacy. Clinical Trial: osf.io; [10.17605/OSF.IO/VFXJK], registered on 30/04/2023

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Version 2 #65682

Abstract

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Conclusion: Phase B will assess the feasibility of the IPS intervention. These findings will then be incorporated into our intervention design and provide the basis for a future randomized controlled trial of its efficacy.

Registration: osf.io; [10.17605/OSF.IO/VFXJK], registered on 30/04/2023

Keywords: health services research; psychosocial intervention; health personnel; Intensive

Care Units; Critical care; Complex intervention; Feasibility study

Introduction

Background

The German healthcare system is well equipped with regard to the number of intensive care unit (ICU) beds. Compared to other European countries, Germany held the highest average rate of 29,9 intensive care beds per 100,000 population capita during the COVID-19 pandemic [1]. However globally, there is a considerable shortage of intensive care unit (ICU) qualified nurses and doctors. Adhering to the legal requirements on minimal care staffing in care sensitive settings in Germany (Pflegepersonaluntergrenzenverordnung) and the recommendations of the German Interdisciplinary Association for Intensive Care and Emergency Medicine (DIVI), the short-staffing of ICU nurses accounts to 45 respectively 74% of all units. In addition in Germany, more than half of the intensive care nurses work part-time, and many are considering leaving the profession [2]. The reasons are diverse, but surely include the special circumstances on ICUs, putting high demands on the health care professionals (HCPs), patients, and relatives, which even get worse under increased short-staffing. The exposure to adverse events like critical incidents in intensive care can lead to second victim traumatising [3]. In a non-representative survey conducted in 2013 among emergency nurses in Scotland, 75% of the sample reported the experience of one or more secondary traumatic stress symptoms in the previous week [4]. Additionally, potentially traumatising events at the workplace are connected to depression, addiction and suicidality as stated in an annual report of the DIVI [5]. A significant number of HCPs in intensive care show psychosomatic symptoms or signs of burnout [6]. Despite the negative impact on HCPs themselves, high stress also puts damage to the healthcare system: Nurses in poor physical and mental health reported significantly more medical errors than nurses in better health [7]. Since the connection between the mental health of practitioners and the quality of care is increasingly considered [8], the circumstances raise a question of patient safety. For patients and their relatives, the ICU is associated with stress and strain pressure. In a systematic review of 42 prospective cross-sectional studies [9], stressors related to disease and treatment (e.g. pain), mental health (e.g. fear of death), communication (e.g. not being able to talk, not knowing enough about one's disease) and ICU environment (e.g. noises, seeing/hearing other patients) were identified. Patients are exposed to multiple potentially traumatic experiences during treatment [10]. The observation that many patients experience new or worsening cognitive (e.g. impairments in memory), physical (e.g. impairment in activities of daily living) or psychological symptoms (e.g. depression) after an ICU stay has even led to the classification of a post-intensive care syndrome (PICS) [11, 12]. In a prospective study conducted in 16 ICUs in Japan, 63.5% of the participating survivors experienced at least one PICS impairment six months after their ICU stay [13]. Psychological symptoms associated with the ICU stay can also be detected in relatives (e.g. anxiety, PTSD or depression), also referred to as post-intensive care syndrome - family (PICS-F) [11], sometimes even more distinct than within patients [13]. The German Association for Neurorehabilitation has recommended applying additional measures in combination to the regular ICU treatment to prevent PICS and to treat already present PICS impairments [14]. These measures shall address physical (e.g. early mobilization), cognitive (e.g. delir prophylaxis) and psychological symptoms (e.g. ICU diaries, improvement of communication and family support). The stress experienced by ICU patients and their relatives may further accentuate the emotional demands on the HCPs, and therefore potentially leading to an increase of the mentioned problems, creating a downward spiral.

From a theoretical perspective, this phenomenon of accumulating stress factors and problems can be explained by the conservation of resources theory (COR) [15]. The COR theory is an integrated, motivational theory of resources with a focus on coping and resource gain. It is based on the

fundamental assumption that people tend to protect their own resources and abilities and strive to build new ones [16]. In this theory, stress is defined as a response to the environment in which the loss of resources is threatened, occurs, or can't be countered by a gain of resources. The COR model particularly implies that (threatened) resource losses can lead to further resource losses, creating a downwards spiral as mentioned above.

On the other hand, also embedded in the COR theory, positive circular processes ("positive gain spirals") describe a salutogenetic process in the sense of positive development and growth. The provision of central resources enables the development and use of further resources: "resources co-travel in resource caravans" [17]. According to the COR theory, the provision of additional resources in the form of integrated psychosocial care could therefore set in motion a positive developmental spiral. The COR theory has already been applied to perceived stress by nurses [18], the aetiology of nurse burnout [19, 20] as well as PTSD development in COVID-19 survivors [20]. While COR theory focuses on resource losses and gains on an individual level, one study also indicates that the loss of resources in nurses, which leads to nurse burnout, should be addressed at an institutional level [19].

A broader perspective of organizational resources as well as demands and their relation to psychological and occupational health is provided by the concept of the Psychosocial Safety Climate (PSC) [21]. PSC refers to employees' perceptions of the extent, to which their organization takes their mental health into account in its decisions (design of working conditions). In alignment with that, nurses who perceived that their worksite was very supportive of their well-being were twice as likely to have better physical health [7]. Interventions consistent with this concept target the causes of stressful working conditions, not just the stress symptoms of the employees themselves. One of its aims is to establish standards of good practice with regard to stress prevention in companies and to develop a specific evidence base for appropriate prevention and intervention strategies [22]. An increasing number of publications show that PSC is positively correlated with variables such as motivation, productivity and self-reported health status, as well as a reduced number of days of absence from work [23, 24]. Simultaneously, PSC shows negative correlations with job and career change intentions [25].

Based on evidence and theory, the need for psychosocial care as an intervention during and after intensive care is undisputed, yet it is only slowly being addressed [26, 27]. Barriers remain high: factors such as time and experience inhibit common use of help [4]. Also, not only patients and their relatives, but ICU HCPs need access to psychosocial care, as demanded [28]. Recently, the Federal Joint Committee Germany published a decision of legal changes to the center regulations for centers for intensive care medicine. It demands "psychological support and crisis intervention for patients and staff available every working day" [29]. However, in the current care landscape of the German health system, there are no integrative structures for the psychosocial care of ICU-teams, the patients and their relatives. To our knowledge, corresponding interventions have never been developed systematically, based on theory and evidence and with the involvement of all stakeholder groups.

First experiences with an integrated psychosocial care concept have been gained in two project member institutions, the Charité Berlin and Ulm University Medical Center, where psychosocial care in ICUs was implemented during the COVID-19 pandemic [30] in response to the increased pressure on ICU HCPs, patients, and their relatives. Through an iterative and needs-focused approach, different psychosocial treatment tools, such as individual counselling, team supervision, health circles, and a survey for efficacy monitoring were selected, developed and carried out with HCPs, patients and their relatives. Specifically in the Charité Berlin, up to 15 psychologists from the Psychosocial Emergency Care department were working on ICUs as part of the HCPs team ("team-integrated"), treating patients, relatives, and HCPs. A total of over 500 end-of-life care sessions were carried out. To this date, three similar interventions have been conducted at the University Ulm. While this makeshift-intervention seems to provoke a positive effect, its design is based solely on clinical experience and its feasibility and efficacy are yet to be empirically evaluated.

Effectively addressing patients, their relatives and ICU HCPs with one intervention would require the development of a complex intervention [31]. Complex interventions specify themselves by several factors, i.e. they consist of several interacting components, they target different groups and different organizational levels simultaneously, a number of different outcomes are expected, and the intervention involves a high degree of flexibility in design. The Medical Research Council (MRC) proposes a framework to develop and evaluate complex interventions, that prioritizes understanding the contextual factors as well as the mechanisms of change, as they depict the connection between the intervention components and the outcome [32]. The development of a complex intervention is based on available evidence and theory and supplemented by participatory measures to include the target group's point of view.

Objectives

This study aims to address the formerly stated stress-related symptoms and consequences primarily in ICU HCPs, but also in patients and their relatives. The objective of the IPS-Pilot project (German: "Integrierte Psychosoziale Versorgung", English: "integrated psychosocial care") is:

- (i) to develop an integrated psychosocial care intervention (phase A) and then
- (ii) assess the feasibility of its implementation and evaluation in a Randomized Controlled Pilot Trial in the ICU setting (phase B).

This protocol reports on phase A.

Our primary research question in this phase is:

How should an integrated psychosocial care concept be designed to meet the specific psychosocial needs of the HCPs in ICU settings, as well as the needs of intensive care patients and their relatives?

Secondary research questions include:

- What are the (psychosocial) needs of ICU HCPs, ICU patients and their relatives?
- What are possible benefits and hurdles of an integrated psychosocial intervention in the ICU?

Our focus lies on determining which needs (psychosocial and other) have to be covered by the intervention to be developed and which hurdles and resources are important for the implementation of the intervention. This shall ensure the best possible practicability in the development of interventions through effectiveness and acceptance by the people affected.

Methods

Responsibilities

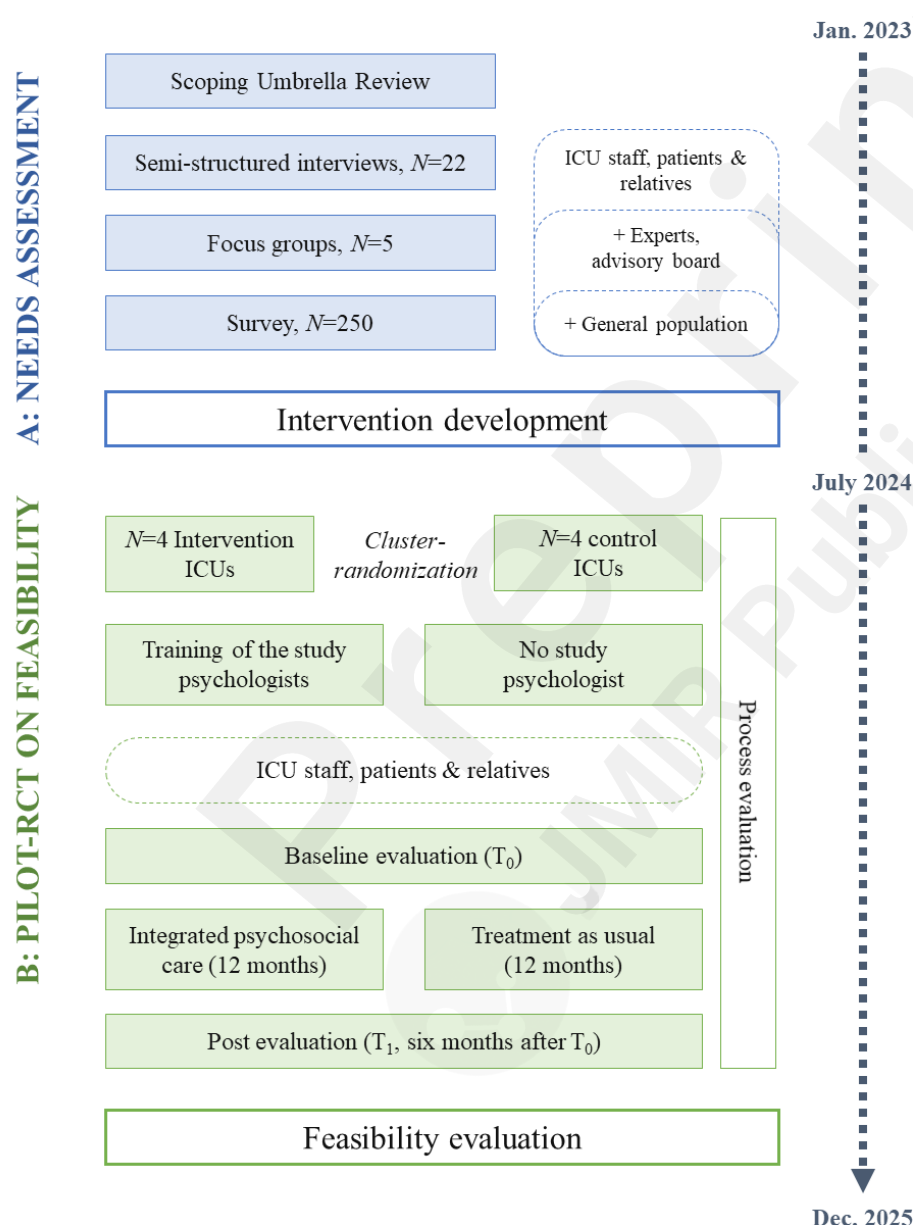
The IPS-Pilot project is coordinated by the Ulm University Medical Center (Department of Psychosomatic Medicine and Psychotherapy) together with the Otto von Guericke University Magdeburg (Institute of Social Medicine and Health Systems Research), the University Medical Centre Magdeburg A.ö.R. (Department of Psychosomatic Medicine and Psychotherapy) and the Charité University Medicine Berlin (Department of Psychosomatic Medicine).

Study design

The following protocol is based upon the SPIRIT guidelines [32] (s. Appendix 1) and Consort statement [33]. IPS-Pilot is a mixed-methods study [10.17605/OSF.IO/VFXJK] that will be conducted in two phases according to the MRC's framework [31] for the development and evaluation of complex interventions, for reference see Figure 1 (Figure 1). The project runs from January 2023 until December 2025. The following protocol focuses on the first study phase (phase A: needs

assessment, intervention development and optimization; January 2023 to June 2024), as the concrete implementation and evaluation concept of feasibility in the second phase (phase B) depends on the intervention that is developed in phase A. As shown in Figure 1, the data collection for phase A and partial analyses for the intervention development were completed by June 2024, whereas the final analyses are yet to be completed.

Figure 1. Overview on the study timeline. Timeline on the right side ranging from start to finish of the IPS-Pilot project and covering phase A and B. Rounded rectangles indicate sample origin. Blue boxes indicate substudies of the needs assessment and intervention development (phase A); green boxes indicate steps of the Pilot RCT on intervention feasibility in phase B which is to be covered in a separate study protocol.



Phase A: Gathering Evidence & Development of Intervention

In phase A, we assess the needs of ICU patients, their relatives and ICU HCPs regarding a psychosocial intervention through evaluation of already existing research (Substudy 1: Scoping

Umbrella Review) and original data collection with qualitative (Substudy 2) and quantitative (Substudy 3) methods. Data from these studies are utilized for the intervention development in the fourth sub-study.

Substudy 1: Scoping Umbrella Review

Registration: <https://osf.io/cb67a>

Numerous studies and reviews can be found on the corresponding needs, whereby the focus is on one of the three perspectives described above. There are reviews focusing on patient needs [34], on the needs of relatives of ICU patients [35] and on those of ICU HCPs members [36]. To our knowledge, there is no overview on all three perspectives. With the scoping umbrella review to be prepared, we will systematically compile and compare studies on the needs and requirements of the different groups of people involved in the ICU treatment. Findings can then be incorporated into the subsequent development of the intervention. The purpose of this scoping umbrella review is to provide an overview of systematically collected and assessed reviews and meta-analyses conducted in the field of needs and demands in the ICU setting. The identified needs will be categorized and in particular the psychological and psychosocial needs of everyone involved in the treatment process will be highlighted and an overview of the current state of research will be provided. The knowledge gained can then form the basis for conceptualizing targeted psychosocial interventions in ICUs.

Inclusion and exclusion criteria

All systematic reviews or meta-analyses that provide a summary of the results of primary studies that assess the needs of people directly involved in the health care in ICUs (patients, their physicians and nurses and relatives) will be included. We will also include reported factors that point out a problem or cause corresponding to a need.

Studies focusing only on pharmacological outcomes in neonatal or pediatric ICUs, or studies conducted only in the context of rehabilitation or palliative care units, will not be included.

Data collection and analysis

The search strategy considers databases comprising both medical (MEDLINE via PubMed, EMBASE via Ovid and Scopus) and social science databases (PsycINFO via Ebscohost). Additionally, we performed a search in Cochrane Database for Systematic Reviews and PROSPERO as database specified for reviews. We are also performing a hand search of reference lists of the assessed reviews. We are searching titles and abstracts based on the research question developed by using the person-content-context-method of the Joanna Briggs Institute [37]. We follow the framework outlined by Levac et al. [38]. Two researchers independently performed screening and selection of titles and abstracts, respectively. Full text versions are obtained and inclusion and exclusion criteria applied. Disagreements can be solved through discussion within the review team. We use a specific form for data extraction, that is developed by researchers and professionals, focusing on the usability of findings for intervention developments. The software ASReview is used for title and abstract screening, and Endnote to manage the literature database. Findings will be narratively synthesized and - if possible - quantitatively assessed and categorized. Categories will focus on study design, perspectives and needs. Reporting will follow the guidelines proposed in PRISMA-ScR [39]. The PRISMA-ScR checklist as well as the search string can be found in the appendix (s. Appendix 2).

Substudy 2: Interviews & Focus Group Discussions

Registration: <https://osf.io/2vfhx>

In order to evaluate ICU related stress factors and needs regarding the intervention in all three target groups, individual interviews were conducted with former ICU patients, relatives of former ICU patients and ICU HCPs from Germany. These insights were then further discussed in focus groups in which HCPs, former patients, relatives, psychologists and experts were interviewed about the demands for contents and implementation circumstances of an integrated psychosocial intervention in ICUs. Research questions were explorative and thus non-directional. The primary research question of this substudy was to determine psychosocial needs in intensive medical care from the patient's, relatives and HCPs' perspective. Secondary research questions aimed at exploring support factors and barriers to the use of integrated psychosocial intervention and design requirements to make an integrated psychosocial intervention approachable for subjects affected. The goal was not to find convergent perspectives, but to collect information from different perspectives in order to gain a vivid and comprehensive representation of the phenomenon of interest.

Sample and eligibility criteria

We conducted interviews with ICU HCPs, former ICU patients and relatives of former ICU patients as well as focus group discussions, each with up to $N=6$ participants, who either belonged to one of the three formerly mentioned groups, had working experience as an ICU integrated psychologist or had administrative expertise (such as controlling, clinic directors). We aimed at including both patients, relatives and HCPs with and without experience in regard to interacting with an ICU integrated ward psychologist. Study participants had to be at least 18 years old and give informed written consent to the scientific staff conducting the interview. We only included patients and relatives who have experienced treatment in the participating ICUs (Berlin, Magdeburg, Ulm) within the last 6 months at the time of inclusion. Included ICU HCPs differed in their work experience and profession (nurses, doctors from different hierarchies). Subjects were recruited by approaching them directly in the context of their treatment or occupation in the ICUs of the participating hospitals.

Data collection

Before the data collection, a test interview was conducted. The interviews and focus group discussions were carried out face to face or online via data protection-compliant video conferencing systems at the three study sites in Germany by project staff trained for qualitative data collection. They were audio-recorded using a recording device and transcribed by a qualified external contractor. For conducting the interviews and focus group discussions, semi-structured questions were developed. The guiding questions were adapted during data collection if necessary. For both the interviews and the focus group discussions, socio-demographic data (e.g. age, gender, work position and experience in ICU HCPs) of the participants were collected for a better classification of the results after each interview/focus group discussion using a standardized questionnaire to be filled out under a pseudonym. The interview and focus group guides can be found in Appendix 3.

Data analysis

Depending on the different questions, the data material is analyzed through qualitative content analysis [40] using MAXQDA. For the interviews, a first code system was developed deductively based on relevant literature [40] and previously identified topics. It was further amplified inductively in the process of the analysis of the first five interviews (5/22, 22.7%). The remaining material was coded by two independent researchers and validated consensually. If occurring differences couldn't be cleared via discussion, the results were presented to a third team member in order to find a solution. For the focus group discussions, the same procedure will be applied, the category system

will be based on the final code system for the interviews. We aim to achieve a methodologically controlled analysis procedure and high quality of the data analysis through communicative, interdisciplinary validation in the research team.

Substudy 3: Survey

Registration: <https://osf.io/a6vct>

In Substudy 3, an online questionnaire survey was conducted to round up the data of needs collected in Substudy 1 and 2. Its goal was to quantify the before mentioned needs. Additionally, known and utilized care models were surveyed, including the frequency and nature of their utilization, as well as obstacles in the implementation of a possible intervention.

Sample and eligibility criteria

The target sample size was $N=250$ participants. Participants had to be at legal age, be able to fill out the questionnaire and informed consent had to be obtained. The substudy aimed at quantifying and comparing psychosocial needs among four groups: former ICU patients, relatives of former ICU patients, ICU HCPs and general population. We planned on recruiting at least $N=50$ participants in each of the four groups. Participation in the survey was anonymous and voluntary.

Data collection

There were four different sets of partially overlapping questionnaires, adapted to each of the four target groups. Participants were presented with a number of individually developed questions, as well as items from validated questionnaires, depending on which of the four groups they were administered to. Through consecutive filter questions on the participant being an ICU patient within the last three years, relative of a former ICU patient, HCP currently working in the ICU or none of the above, participants were allocated to one of the four groups described above. Figure 2 shows the allocation procedure and the administered questionnaires depending on the group.

Figure 2. Overview on the administered scales [41-51] in the questionnaire depending on group allocation by filter questions.



The survey was conducted and evaluated digitally and anonymously using Limesurvey online [52] with recruitment through German professional societies, interest groups, and other suitable channels. A pretest with $N=20$ participants was conducted to assess comprehensibility and feasibility.

Data analysis

We will use descriptive statistics to analyze and report the findings, considering differences in psychosocial needs and support among participant groups. As all analyses are exploratory in nature,

no hypotheses were specified. Exploratory analyses may involve examining patterns of psychosocial needs and support across demographic variables. Missing data will be handled by reporting the available data without imputation.

Substudy 4: Intervention development and optimization process

For the intervention development we planned an extensive multi-step participatory process. This process is structured based on the framework of the MRC [31, 53]. The precise steps rely on the Intervention Mapping (IM) framework [53]. For this, the obtained evidence from Substudies 1, 2, and 3 was summarized and integrated with each other to ensure a broad understanding of the needs of our target groups. Figure 3 provides an overview of the synthesis process. For example, in step 3 of the IM Framework, effective interventions in ICUs identified within the scoping umbrella review (Substudy 1) were listed, organized, discussed and selected by the research team on the basis of potential feasibility in German ICUs. In the context of one of three workshops, this selection of intervention tools was compared and supplemented by the findings from the interviews and focus groups on desired interventions (Substudy 2). The evidence was then mirrored with and incorporated into our model of change, therefore being synthesized with our theoretical approach – the resource-oriented viewpoint of the PSC [21] and COR [16] theory. Next, a first draft of the intervention was developed according to the IM concept [53], within the scientific study team and in close cooperation with experts. Within this process, three online and face-to-face workshops were carried out, with the inclusion of members of the study team and stakeholders (former ICU patients and relatives as well as different representatives of HCPs, e.g. physicians, nurses, therapists). Stakeholders were selected for participation and approached personally by the study team, e.g. as members of the IPS-Pilot advisory board. The goals of these workshops were to 1) elaborate the logic model of change, modelling the interrelationships and the responding intervention components (IM Step 2), 2) select intervention components that have already been evaluated in previous studies (Substudy 1) or suggested by target groups (Substudy 2; IM Step 3), and 3) to accurately review and further specify the intervention draft as well as the planned implementation process with the stakeholders (IM Step 4). For this substep, methods of the design thinking approach [54] were used, namely the Disney Strategy [55] which has previously been applied in various program and intervention design processes, also with the participation of stakeholders [56, 57]. Discussion topics included the description, timing, scope, or further framework conditions of intervention components. The final draft of intervention tools was then specified by the survey (Substudy 3), in which the needs were quantified. The resulting psychosocial care intervention is primarily linked to the condition of being delivered by a clinically experienced psychologist (in psychotherapeutic training; hereinafter called: IPS therapist) with a 50% deputation, who will be an integral part of the permanent ICU HCP team for the duration of the intervention. Single additional components of the complex intervention may be delivered by other HCPs under the condition of local availability. The final concept (hereinafter called: IPS intervention) will be documented in form of an intervention protocol and an intervention manual which will contain instructions on the interventions to be administered by the IPS therapist.

Figure 3. Synthesis and integration process of the sub-studies (left column) and their respective outcomes as well as theoretical and empirical input (middle column) into the steps of the IM process (right column).

Patient and Public Involvement

In all substudies the perspectives of our target groups – ICU HCPs, patients and their relatives – are collected and included. In Substudy 1 their needs are included indirectly through research on already existing studies. In Substudy 2 and 3, they are directly included as participants in the interviews and focus groups as well as in the survey. In our fourth and last Substudy we invited all perspectives to participate in workshops where the concrete intervention design was discussed. Over the course of the whole project, we will continue to include our target groups in our advisory board.

Outlook on Phase B: Pilot Study

The feasibility of a pilot RCT on the IPS intervention to be developed in phase A will be evaluated in a multi-center study involving three sites in Germany. In the university hospital in Berlin, Magdeburg and Ulm, eight non-specialized ICUs for adults will be selected. Via a randomized cluster design, four ICUs will be assigned to the intervention group, four to the control group. Over the course of 12 months, psychologists in psychotherapeutic training will be admitted each to one of the four intervention ICUs as an IPS therapist from Mid 2024 until Mid 2025. Meanwhile, a survey with two measurement points is carried out on all participating wards with HCPs, patients and relatives to evaluate feasibility criteria like participation rate or practicability. A separate study protocol on phase B will be submitted and pre-registered. Further descriptions on methods and endpoints can be found in this study protocol.

Ethics and Dissemination

With regard to scientific quality, the guidelines for ensuring good scientific practice of the German Research Foundation as well as Good Epidemiological Practice [31] were adhered to.

Research ethics approval was obtained via the Ethics Committee of the University of Ulm (108/23-FSt/Sta) and the University Medical Centre Magdeburg (34/23), which were recognised as valid by the Charité-Universitätsmedizin Berlin in accordance with §15 Section 2 Professional Code of Conduct of the Berlin Medical Association [58]. Modifications of the study plan as described above were communicated with the ethics committees as well as the funder, and permission for the modifications was obtained where necessary.

The EU General Data Protection Regulation and the Federal Data Protection Act apply to data protection. A data protection concept has been formulated according to these guidelines with specific regard to the planned methods of data collection, storing and analysis and has been approved by the data protection managers in the Ulm University Medical Centre. Advice on the procedure was obtained from the Center for Clinical Trials Ulm. Registrations of processing activities were carried out at all sites. A trustee office has been set up to ensure a secure transfer of data. Person-identifying data were only be collected if necessary (e.g. for data withdrawal after participation). This data was only transferred between the parties involved by messenger. Pseudonyms or personal data were never transmitted via an unencrypted Internet connection or any other medium.

The trial was conducted according to the Declaration of Helsinki. Informed written consent was obtained from all participants (s. Appendix 4). Participants were informed that their participation is voluntary and can be discontinued or cancelled at any time before, during, or after participation. No payment was provided for participation.

Results

The development of the IPS intervention was completed by the beginning of June 2024. Due to the timeframe, analyses of the substudies at this time were only partly completed with the focus on psychosocial stressors and needs to be included in the intervention design. Through the four substudies we aimed to establish a logic model of the problem and a logic model of change. Together they describe the psychosocial needs of ICU patients, their relatives and ICU HCPs and explain how the hereby caused stress in ICUs could be tackled and effectively reduced through a complex psychosocial intervention. In order to formulate those models we collected, compared, classified, quantified and will further analyze the demands and needs from the three different perspectives. Final results of the individual substudies will be reported separately in 2025.

Data collection and analysis for the scoping umbrella review (Substudy 1) is yet to be completed, due to the breadth of the included studies. A total of $N=109$ studies on psychosocial needs as well as existing psychosocial interventions were included in the synthesis for the intervention development. In a next step, the included studies will be analyzed in more detail with regard to psychosocial needs and requirements. The final analysis of the scoping umbrella review will be completed in 2025.

Interviews and focus groups (Substudy 2) were completed in November 2023, respectively March 2024. We conducted interviews with $N=10$ ICU HCPs, $N=6$ former ICU patients and $N=6$ relatives of former ICU patients as well as $N=5$ focus group discussions with $N=18$ participants in sum. Analysis of the interview data was completed in August 2024, analysis of the focus groups is expected to be completed by April 2025. The survey (Substudy 3) was conducted from April to June 2024 and collected data from $N=51$ ICU patients, $N=52$ relatives, $N=73$ ICU HCPs and $N=61$ participants from the general population. Analysis of the data was completed in October 2024. The workshops in Substudy 4 were conducted in March ($N=11$ participants), April ($N=15$ participants), and May of 2024 ($N=20$ participants). The intervention manual was completed in the beginning of June 2024.

Discussion

This study protocol provides an overview of a structured, theory-guided, multi-method, participatory approach for designing an integrated psychosocial intervention in ICUs in the framework of the IPS-Pilot project. The methods described in the protocol are expected to lead to a deeper understanding of the psychosocial needs of our target groups and therefore a best possible fit of the resulting IPS intervention.

During the COVID-19 pandemic, the public awareness of psychosocial burdens and needs of HCPs, patients, and relatives in the ICU context increased. To deal with the growing pressure on the formerly mentioned groups, a makeshift intervention in form of a psychologist working as part of the ICU team was installed in Berlin Charité and Ulm University Medical Center. Our experiences gained during the pandemic indicated that all groups benefited from this complex psychosocial treatment. Yet, there is a lack of scientifically gained evidence on the psychosocial needs to be addressed through a complex intervention in the ICU context, its optimal design, feasibility, and lastly effectiveness.

This study protocol aims at making the development process of the IPS intervention accessible. A limitation of the intervention development process stems from the complexity of the development process itself. Because all of the steps described in the IM framework [53] required a synthesis of theory as well as existing and newly generated evidence, the procedure and analysis of our interdependent substudies were constrained by a tight timeframe. This timeframe may seem at odds with intervention development frameworks, which call for a dynamic rather than linear development process [31, 53]. Therefore, to avoid delays and to ensure a sufficient knowledge synthesis, intermediate or partial analyses of data and repeated feedback loops between substudies were necessary. This required sufficient time resources and close collaboration within the scientific team.

It is known that there exists a high stress burden on HCPs, and naturally, also in a different way on patients and their relatives. Based on interacting theoretical concepts of individual [15, 16] and structural stress [17, 21], the stress perceived by those three groups seems to be interconnected. On top of the possible interdependence of the three groups, there are also differences in their perception of different stressors, such as the perceived importance of post-ICU outcomes (e.g. survival rate), which makes the need for an intervention that can include the perspectives of patients, relatives and HCPs and mediate between them even more apparent [59]. There is empirical evidence on the efficacy of intra-ICU psychological care, e.g. for reducing post-ICU depression, posttraumatic stress disorder and anxiety [60, 61]. However, all controlled trials on interventions on stress-reduction in ICUs known to us, focused only on parts of these groups, e.g. patients [62], relatives [63] or HCPs [64], until now. To our knowledge, IPS Pilot is the first project to systematically assess psychosocial needs in ICUs and to develop and evaluate a complex intervention addressing these needs for all groups involved at once via a participatory process, based on theory and grounded in evidence.

It remains to be examined whether the integrated and simultaneous psychosocial care for those groups is beneficial or comes with difficulties or even adverse effects. On the background of prior experiences in Berlin and Ulm, the team integration of a psychologist in ICUs seems to be accepted, perceived as helpful, and frequently used by HCPs, patients and their relatives. Integrating psychological care combined for patients and professionals in the ICU context has also been demanded by professional associations, and legal committees, and, from our experience, the involved groups themselves (e.g. staff members).

In a non-experimental evaluation of patient and relative surveys and data conducted in Brazil [65], different roles of psychologists working in an ICU are highlighted. Not only can ICU psychologists help patients and their relatives in dealing with stress and negative emotions experienced while in the ICU treatment. In addition, psychosocial care may also support HCPs in dealing with individual as well as work induced stress. The authors conclude that psychologists integrated into ICU teams can help enhance team relationships and communication among HCPs, patients, and their relatives. A

review on the role of psychologists in pediatric ICUs in Britain implies that through the team integration and the mere presence, psychological factors may be more considered by the ICU team and through easy approachability, the ICU psychologist can be sought for advice on personally demanding cases or for short debriefing sessions by the HCPs [66].

On the other hand, one could argue that consulting the ICU team or team members individually while treating patients and their families as part of the interdisciplinary team could result in a role conflict and impact the professional independence of the psychologist. Team members may be reluctant to seek advice from a team-integrated psychologist due to an unclear perception of the psychologist's role or concerns for confidentiality or stigmatization in the team as research on acceptability of workplace-integrated psychotherapeutic consultation suggests [67]. Similar difficulties may arise if supervision due to a team conflict is needed. Moreover, HCPs could fear to be seen seeking the psychologist for advice, a limiting factor previously identified in studies on the use of psychological consultation in the workplace [68]. Through the inclusion of stakeholders at multiple points of our intervention development process, we aimed to identify these and other possible problems in the implementation of the intervention and search for possible solutions, e.g. outsourcing conflict-laden multi-person interventions to external supporters. Based on the experiences of the research team and the insights gained from former ICU ward psychologists in the focus groups we will also include measures to support the IPS therapists in the evaluation phase, e.g. supervision and intervision. Evidence described above surely highlights the importance of a careful, trusting approach with a high level of confidentiality, and the need to take possible role conflicts and the role of the psychologist itself into consideration. These factors, which may limit the feasibility of the IPS intervention, were considered in the development process and will also be surveyed and evaluated in the feasibility study, which is to be described in detail in the study protocol on phase B of the IPS-Pilot project.

In conclusion, there is a lack of systematically gathered evidence on how a complex, team-integrated psychosocial intervention on ICUs shall be ideally designed, and if the result of such an intervention designing process proves to be feasible and effective. Through a multi-methodical approach, we hope to gain a broader insight into the needs of our target groups. Difficulties in phase A resulting from our choice of methods and our targeted samples will be monitored and included in the feasibility analysis in phase B.

Through a feasibility trial, the conditions that contribute to the success of the implementation of the intervention and therefore enable to execute its mechanisms of change can be explored. Based on the results of phase B it shall then be determined whether a randomized controlled trial on efficacy of the IPS intervention is feasible and should be conducted. Although our study is conducted solely in Germany to assess feasibility in this specific health care context, the IPS intervention may be applicable in other health care contexts as well. The similarity of the IPS intervention to examples from other countries, such as Brazil [65] or the United Kingdom [66] shows the international interest and relevance of psychosocial support in ICUs. Furthermore, as the development of the IPS intervention is based not only on a needs assessment in German samples, but also on international evidence gathered in the Scoping Umbrella Review and internationally applied stress theories [17-24], there is reason to believe in its generalizability and potential for international feasibility.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author or principal investigator upon reasonable request.

Participants can assign themselves to a mailing list if they are interested in updates on and results of the study. The results of the substudies will be made public via scientific publications and presentations on conferences for ICU HCPs and in the field of healthcare research in general. Deidentified individual clinical trial participant-level-data (IPD) cannot be shared due to strict ethics committee and staff council regulations.

Authors' contributions (roles and responsibilities)

The coordinating centre of IPS-Pilot is the Ulm University Medical Center (Department of Psychosomatic Medicine and Psychotherapy). HG is the Principal Investigator of the trial consortium. CA, FJ and MR are the PIs of the collaborating study centres.

Authors' contributions according to CRediT [69]:

PD, SN, HG, CA, FJ, MR were responsible for conceptualization and funding acquisition.

SN, SK, GK, KS, LE, JK, LS, HH, WS, MB, SP, KN, JG were responsible for investigation.

HG, CA, FJ, MR, WS were responsible for methodology.

SN, SK, CH were responsible for project administration.

HG, CA, FJ, MR, KH were responsible for supervision.

SN and SK were responsible for writing the original draft.

SN, SK, GK, LS, JG, WS, HH, PD, CA, HG were responsible for review & editing

All authors approved the final version.

The funder, G-BA, has contributed to the study design. However, it has no role in data collection, management, analysis, interpretation or reporting.

Conflicts of Interest

None declared.

Abbreviations

COR: Conservation of Resources

DIVI: German Interdisciplinary Association for Intensive Care and Emergency Medicine

HCP: Health Care Professional

ICU: Intensive Care Unit

IM: Intervention Mapping

IPS: Integrated Psychosocial Care (german: Integrierte Psychosoziale Versorgung)

MRC: Medical Research Council

PICS: Post-Intensive Care Syndrome

PICS-F: Post-Intensive Care Syndrome: Family

PSC: Psychosocial Safety Climate

Appendix

Multimedia Appendix 1: SPIRIT checklist

Multimedia Appendix 2: PRISMA-ScR checklist and search string of the Scoping Umbrella Review

Multimedia Appendix 3: Interview and Focus Group Guides

Multimedia Appendix 4: Sample Participant Information and Consent form

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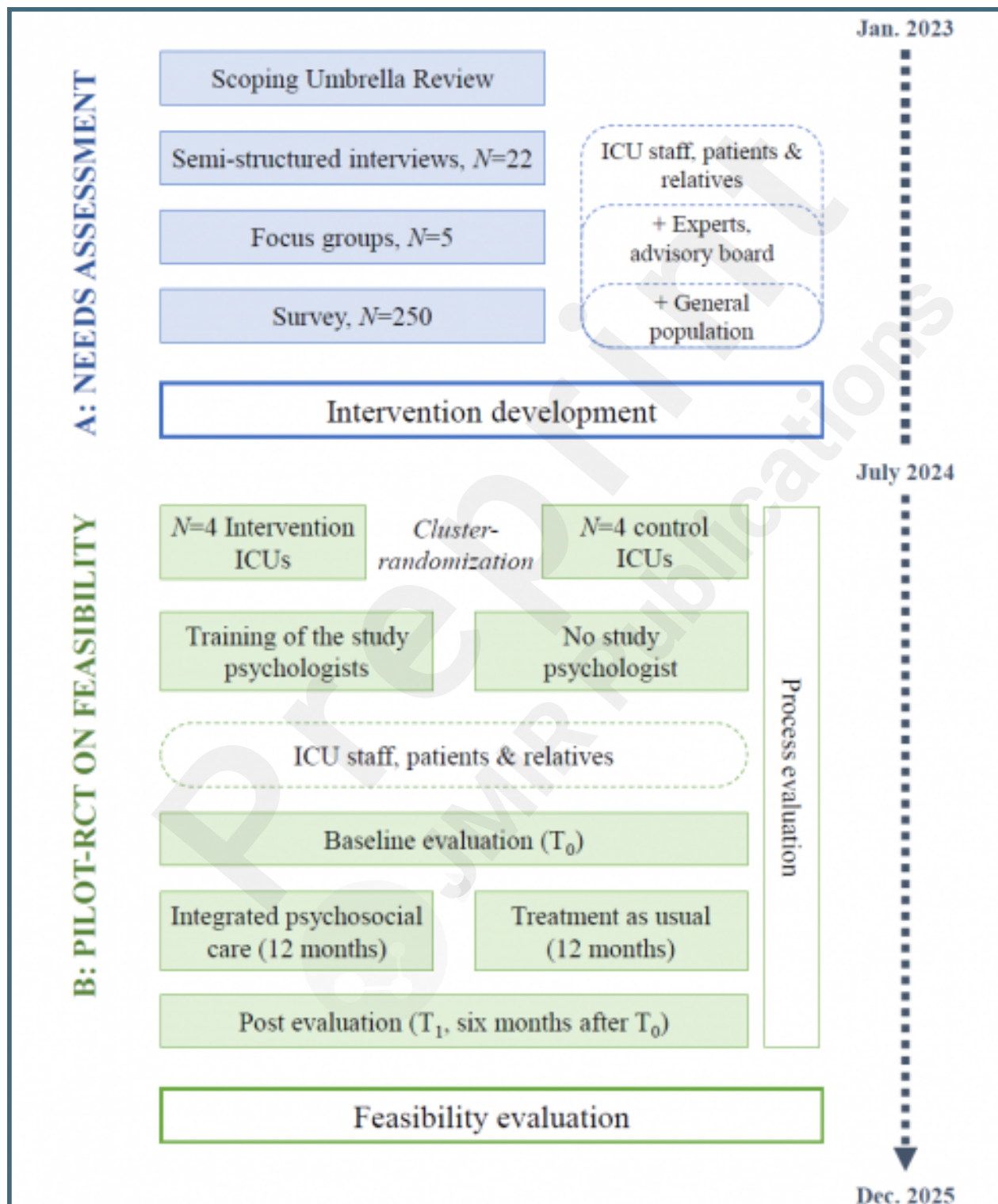
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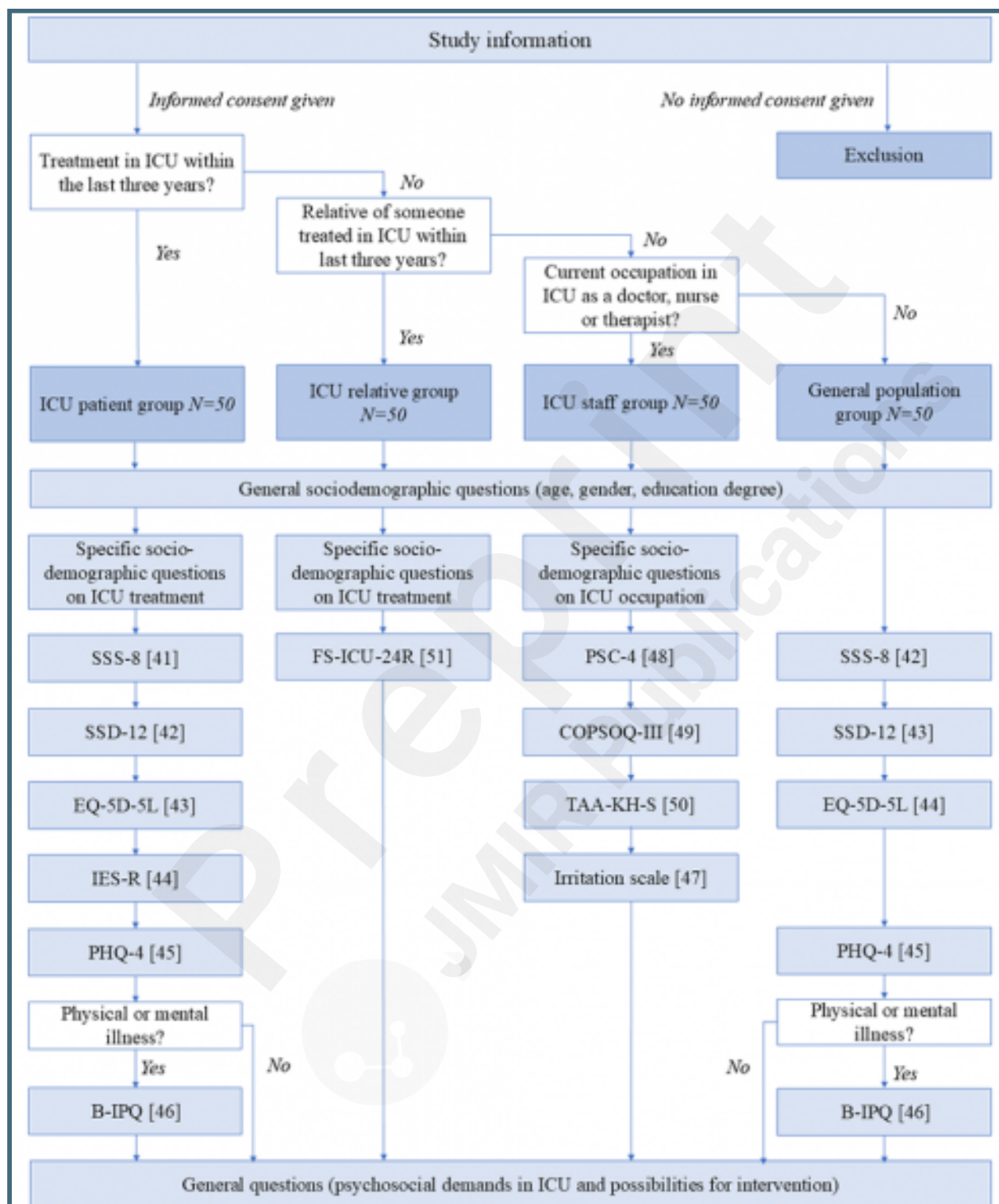
Supplementary Files

Figures

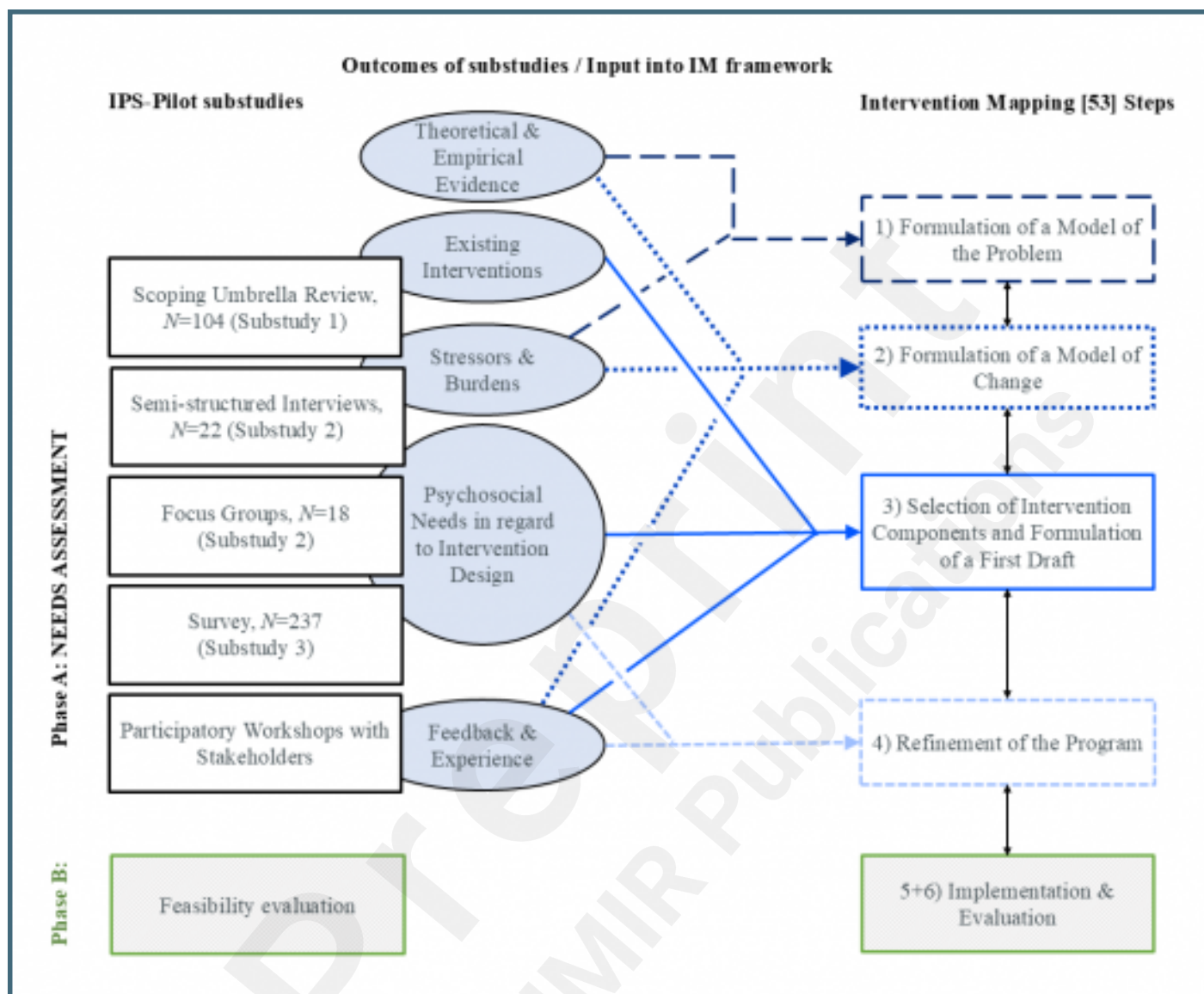
Overview on the study timeline. Timeline on the right side ranging from start to finish of the IPS-Pilot project and covering phase A and B. Rounded rectangles indicate sample origin. Blue boxes indicate substudies of the needs assessment and intervention development (phase A); green boxes indicate steps of the Pilot RCT on intervention feasibility in phase B which is to be covered in a separate study protocol.



Overview on the administered scales [41-51] in the questionnaire depending on group allocation by filter questions.



Synthesis and integration process of the sub-studies (left column) and their respective outcomes as well as theoretical and empirical input (middle column) into the steps of the IM process (right column).



Multimedia Appendixes

SPIRIT checklist.

URL: <http://asset.jmir.pub/assets/54347bc35a98b155b953c14adb893c9d.pdf>

PRISMA-ScR checklist and search string of the Scoping Umbrella Review.

URL: <http://asset.jmir.pub/assets/d0292afc36c6e6e0c5180aaf45d61d11.pdf>

Interview and Focus Group guides.

URL: <http://asset.jmir.pub/assets/3019d4255fb41c5a08ca062e0ae74b92.pdf>

Sample Participant Information and Consent form.

URL: <http://asset.jmir.pub/assets/0c88789cd361b486d38aa2a0340e50a9.pdf>



CONSORT (or other) checklists

CONSORT eHealth Checklist.

URL: <http://asset.jmir.pub/assets/9d8d8797f6fffaa8567d344e978ed810.pdf>