

International Journal of Therapy and Rehabilitation

The patients', family members' and carers' perspective of the barriers to, and facilitators of, early mobilisation for ICU-Delirium: A qualitative Study Protocol --Manuscript Draft--

Manuscript Number:	ijtr.2021.0020R1
Article Type:	Original research
Keywords:	Humans; Early Ambulation; Caregivers; Family; Intensive Care Units; Delirium
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BAFTA-ICU: The patients', family members' and carers' perspective of the Barriers And Facilitators of locomotion for a Delirium population in the Intensive Care Unit.

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Background One third of patients develop delirium following intensive care unit (ICU) admission. ICU-delirium is associated with poor patient outcomes including long-term disability and high mortality. Early mobilisation contributes towards the prevention and reduction of ICU-delirium. However, the implementation of early mobilisation is infrequent.

Aims To explore the key participant's experience of the barriers to, and facilitators of, early mobilisation in the adult ICU specific to a delirium population.

Methods and analysis Three moderators will carry out up to six focus groups including up to five participants in each group. Focus group discussions will be utilised to explore the experiences of patients, carers and family members using Microsoft Teams. Participants will be recruited using a purposive sampling technique from the ICU support groups.

Discussions will be audio-recorded and simultaneously transcribed verbatim utilising the otter.ai program. Framework analysis using a thematic methodology will identify themes in the data.

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INTRODUCTION

The James Lind Alliance Intensive Care Priority Setting Partnerships, informed by patients, carers and healthcare professionals, suggest the third top national priority for intensive care is the monitoring and management of ICU-delirium (JLA, 2014). This supports the best practice guidelines for management of delirium in the intensive care unit (Devlin, et al., 2018). Delirium is an umbrella term used to describe an acute brain dysfunction (European Delirium Association, American Delirium Society, 2014). It is identified according to the Diagnostic and Statistical Manual of Mental Disorders fifth edition (DSM-V) criteria and is most commonly diagnosed using validated tools known as the Confusion Assessment Method in the Intensive Care Unit (CAM-ICU) and the Intensive Care Delirium Screening Checklist (ICDSC) (Glass, 2013; Gusmao-Flores, et al., 2012). There are three main sub-types of delirium; hyperactive, hypo-active or mixed delirium which are classified using the validated Delirium Motor Subtype Scale (DMSS) (Meagher, et al., 2008; Boettger, et al., 2017). The clinical practice guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility and Sleep Disruption (PADIS) highlight a threefold increase in mortality rate at six months in relation to ICU-delirium patients (Devlin, et al., 2018). Evidence suggests up to one-third of patients admitted to the ICU develop delirium (Salluh, et al., 2015). Furthermore, the severity of illness and associated mortality rate has demonstrated a substantial cost to health services (Vasilevskis, et al., 2018). Delirium usually develops due to an underlying physiological response to a medical condition and may be multifactorial in nature. These modifiable factors may include causes such as an infection, pain, drug or alcohol withdrawal, sedation, disturbances of circadian rhythm or immobilisation (Devlin, et al., 2018; Hsieh, Ely and Gong, 2013). Evidence suggests the outcomes of ICU-delirium are poor throughout their intensive care and hospital admission such as, increased risk of death and longer stays as well as cognitive impairment following discharge (Salluh, et

al., 2015). These findings are concerning because ICU-delirium is a reversible condition (Salluh, et al., 2015). Furthermore, an article written by a previous patient who had suffered from ICU-delirium provides further insight into the detrimental long-term impact upon patients and their families such as recurrent hallucinations and emotional distress (Garrett, 2019).

Current guidelines recommend pharmacological and non-pharmacological interventions to prevent and manage delirium (Devlin, et al., 2018). These include early mobilisation as part of the ABCDEF bundle and/or as a single intervention for critically ill patients. The ABCDEF bundle includes the following management and treatment; Assess, prevent and manage pain; both spontaneous awakening and breathing trials; Choice of sedation; Delirium: assess, prevent and manage; Early Mobility; Family engagement and empowerment. Currently the definition of early mobilisation across the literature is diverse and inconsistent. Therefore, there is no standardised definition of early mobilisation at present (Clarissa, et al., 2019). A concept analysis described mobilisation as “a type of intervention within rehabilitation that facilitates the movement of patients and expends energy with a goal of improving patient outcomes” (Amidei C, 2012). For the purpose of this study, early mobilisation will be defined as mobilisation such as in-bed or out of bed physical activities, initiated as early as possible during ICU admission (Parry, et al., 2016). Evidence has demonstrated early mobilisation is an efficacious, safe and achievable intervention for mechanically ventilated patients (Hayhurst, Pandharipande and Hughes, 2016; Reznik and Slooter, 2019). Despite this evidence and the clinical practice guidelines concerning early mobilisation, application of early mobilisation remains infrequent (Sibilla et al., 2020; Fontela et al., 2018; Jolley et al., 2017).

RATIONALE

The concern for the treatment and prevention of ICU-delirium is a high priority recognised by patients, carers and health professionals in the United Kingdom (JLA, 2014). Therefore identifying, evaluating and understanding effective implementation of early mobilisation to contribute towards the prevention and reduction of ICU-delirium is important.

A qualitative study in Spain explored the experiences of doctors and nurses concerning the management of delirium in the ICU across five intensive care units in four hospitals (Palacios-Ceña, et al., 2016). Thematic analysis identified three themes; the professional perspective on delirium, implementing pharmaceutical and non-pharmaceutical treatment for delirium and work organisation in the ICU. The results demonstrated staff's own beliefs, professional relationships and their ways of working determined implementation of treatment and management of ICU-delirium. This study described a context specific to the Spanish ICU setting which did not utilise local ICU protocols in clinical practice. This may limit transferability across international contexts. However, similar findings were demonstrated in a qualitative study utilising eight focus groups comprising of 24 nurses and 15 doctors from five medical-surgical ICU's across Denmark (Collet, Thomsen and Egerod, 2019). Pharmacological treatment and non-pharmacological interventions were determined by individuals' personal preferences, experience and the use of a protocol. A sub-theme identified the differing perceptions on the management of the different hyperactive and hypoactive delirium subtypes. For example, hypoactive delirious patients were perceived as safe therefore, they were not a cause of concern for ICU staff. **These studies may suggest clinician perception may be a potential barrier to understanding the patient experience of delirium and understanding the role of preventative interventions such as early mobilisation to improve patient outcomes.**

Bohart, Moller and Herling (2019), explored the experiences of 11 Danish ICU-delirium patients' relatives, utilising semi-structured interviews and a phenomenological approach. The three main categories highlighted were: delirium was not perceived as a main concern of relatives and staff, communication with health professionals is crucial and delirium impacts upon relatives. Patients' relatives perceived delirium as a secondary problem since, health professionals did not talk about delirium. Therefore information was requested and the relatives felt uncertain of the patient's future. Current research has explored the experiences of ICU-delirium management from the perspectives of nurses, physicians and patients' relatives. Rycroft-Malone (2004), explain clinicians' consideration of the patient experience demonstrates evidence-based practice and patient centred-care alongside research, clinical experience and the local context. Deacon (2012), explored the patient experience of rehabilitation following ICU to discharge utilising a qualitative open-question survey study. Patient reported themes

identified were issues relating to: information and education; personal support and assessment and therapy. Patients felt they needed information on what happened to them and expectations of recovery e.g. what is normal? Patients reported they wanted more physiotherapy input and psychological support such as support groups following hospital discharge. This study utilised an open survey method and one independent researchers' interpretation which may limit capturing the patient experience compared with focus group discussion or interviews. Furthermore, participants were of a general ICU population and were not specific to an ICU-delirium population. However, these findings potentially contrast IU clinicians' perception of delirium management such as early mobilisation and patients and their relatives perceived experiences. Therefore, these findings provide some understanding of the patient experience and their perceived needs for clinicians to consider when delivering complex interventions such as early mobilisation in order to improve patient-centred care.

To the authors' knowledge, there is currently no evidence exploring the complexities around implementation of early mobilisation in the ICU specifically concerning a delirium population from the patients', family members' and carers' perspective. Therefore, the aim of this qualitative study is to explore the key participant's experience of the barriers to, and facilitators of, early mobilisation in the adult ICU specific to a delirium population. We anticipate the results identified will contribute towards improving implementation of early mobilisation as part of the prevention and management of delirium in the adult ICU.

AIM

The aim of this qualitative study is to identify and explore patients', family members' and carers' experiences' of the barriers to, and facilitators of, early mobilisation in the adult ICU specific to a delirium population utilising virtual focus groups.

OBJECTIVES

- To explore the patients', family members' and carers' experience of early mobilisation in the ICU environment specific to an ICU-delirium population.

- To understand the perceived barriers to, and facilitators of, early mobilisation for an ICU-delirium patient population.
- To investigate the patients', family members' and carers' perceived influencing factors of implementing early mobilisation such as different clinician groups within the ICU e.g. nurses, physiotherapists or the types of activity(s) of early mobilisation e.g. in-bed, out of bed activities.

OUTCOME

To understand the patients', family members' and carers' perception of early mobilisation and the factors potentially influencing implementation of early mobilisation in the ICU for a delirium population.

METHODS

The theoretical framework for this study will be informed by guidance developed concerning qualitative research design and methodology (Moser and Korstjens, 2017a; Korstjens and Moser, 2017b; Moser and Korstjens, 2017a; Moser and Korstjens, 2017b). Framework analysis incorporating a thematic methodology will be followed by Ward and Braun and Clarke (Ward, et al., 2013; Braun and Clarke, 2006; Braun and Clarke, 2014). The qualitative design of this study will provide richer understanding for implementing early mobilisation for ICU-delirium patients from the service users' perspective (Denny and Weckesser, 2019). A phenomenological approach utilising focus groups will explore the service users' perspective of early mobilisation in the ICU environment. This approach involves the study of the experience of a phenomenon (e.g. early mobilisation) in the ICU for a specific population (e.g. delirium). Participants share the experience of the phenomenon (e.g. early mobilisation) but are not limited to specific characteristics (e.g. gender, ethnicity). Therefore this approach will address the aims and objectives of this study and provide rich content and representation of the patient population concerned. Please see appendix A for the project timeline.

Location

Due to the current COVID-19 guidelines and restrictions for social distancing measures all data will be collected via Microsoft Teams, a virtual video-conferencing platform. Microsoft Teams has been found to

be a feasible data collection tool for qualitative research by **St. George's University Research Ethics Committee (SGREC)**. Microsoft Teams allows for whole group communication in order for the moderators to provide introductions, explain the study aims and objectives, ground rules, consent, data collection, data analysis processes as well as expectations such as start and finish times. Following initial communication as a whole group, participants will be placed into smaller virtual groups of three to five participants with an assigned moderator (Lobe, Morgan and Hoffman, 2020). Utilising a virtual platform will mean a number of limitations for participation to the study. **Participants will be restricted by internet access although participants will not be required to download the Microsoft Teams application prior to data collection. Telephone interviews will be offered to individuals wishing to participate in the study but who do not have access to Microsoft Teams. All telephone interviews will be voice-recorded using the Olympus PT-8 Telephone Pick-Up Digital Handset Earphone and microphone and transcribed using the otter.ai program discussed below. Member check approval of transcriptions will be sought from all participants to ensure accuracy of data.**

Study Population

There will be no limit of inclusion of participants according to gender, ethnicity, socioeconomic background and United Kingdom (UK) national location. Paediatric, adolescent service users' will not be included due to the adult (>18 years of age) ICU study population concerned. It is anticipated participants may be restricted to English speakers only due to limited funding for this study. In this case this will be a limitation of the study. However application of funding for translation support to include non-English speakers will be made. This will go some way toward ensuring inclusion and preventing sampling bias. **All participant characteristics such as age, reason for ICU admission and formal diagnosis of delirium will be collected using a participant questionnaire. The questionnaire will be reviewed in consultation with a public advisory group (PAG) to ensure relevance of language and content.**

Inclusion criteria

- Adults (aged >18 years).

- NHS patients following one year of ICU discharge who report developing delirium during ICU admission
- Family members of NHS patients who have suffered/suffering from delirium following one year of ICU discharge
- Carers of NHS patients who have suffered/suffering from delirium following one year of ICU discharge
- Patients who received early mobilisation
- Family members who observed and/or participated in early mobilisation sessions
- Carers who observed and/or participated in early mobilisation sessions
- Live in the United Kingdom

Exclusion criteria

- Patients with neurological conditions such as head injury, stroke or spinal cord injury, diagnosis of dementia.
- Individuals who lack capacity to give consent
- No access to internet or telephone
- Language

Sampling

The sampling strategy for this study will be informed by guidance on sampling, data collection and analysis of qualitative research (Moser and Korstjens, 2017b). The number of participants included in each virtual focus groups will be guided by Lobe, Morgan and Hoffman (2020).

Size of sample

We will aim to carry out four to six focus groups each including three to five participants (Moser and Korstjens, 2017b; Lobe, Morgan and Hoffman, 2020). However, the authors recognise the importance of a flexible approach in qualitative research to ensure the collection of rich content in order to meet the

study aims. This will aid transferability of findings to the context concerned. The degree of flexibility of sample size will be jointly decided by the research team and guided by the content within the data to reach data saturation.

Sampling technique

We will recruit participants using a purposive sampling technique. This involves the selection of the most informative participants that will provide a rich representation of the population and experience(s) concerning the research question (Moser and Korstjens, 2017b). This will be determined by the research team and in consultation with the PAG members.

Participant recruitment process

We aim to recruit adult NHS patients following one year of ICU discharge who suffered from/suffering from delirium, family members and carers in the UK. Due to the design and aims of this study recruitment and data collection will be a flexible process. Recruitment will commence on receipt of ethical approval.

Sample identification

Participants will be recruited with support from PAG members in applying to advertise the study with the corresponding author's contact details on the [ICUSteps patient support charity](#). All potential participants will be emailed patient information and consent forms (Lobe, Morgan and Hoffman, 2020).

INFORMED CONSENT

Informed consent will be in accordance with the Medical Research Council guidelines and World Medical Association Declaration of Helsinki (MRC, 2018; World Medical Association, 2013). Informed consent for online data collection will be obtained by the corresponding author who will email the formal consent form to participants. Participants will be requested to provide consent with an electronic signature on the forms and return via email. This will provide an opportunity for participants to ask any questions via email

prior to consenting (Lobe, Morgan and Hoffman, 2020). All participants will be made aware sessions will be voice-recorded and all participants will be free to leave the session at any point and for any unstated reason during the data collection process by disconnecting from the conference call. This will be made clear in the patient information sheet and consent form.

DATA COLLECTION

This qualitative study will utilise virtual online focus groups audio-recorded on Microsoft Teams, a virtual platform. Each focus group will be between 90 to 120 minutes in duration (Moser and Korstjens, 2017b). Guidance regarding virtual data collection methods, for qualitative research during the COVID-19 pandemic will be with reference to Lobe, Morgan and Hoffman, (2020). The Microsoft Teams hosts more than 50 participants and will be audio-recorded using an exclusive account of one of the moderators. This is a private, password protected free account therefore there will be no incurred costs for it's use. Three independent moderators will follow a pre-determined moderator script but will allow flexibility to facilitate focus group discussion and relevant topics to appear. The content of the moderator script will be co-produced with the research team and the PAG. Please see table one for examples of discussion topics determined with a public member on the research team. These will be further developed with the PAG. A pilot focus group utilising the moderator script will be carried out prior to the formal data collection process. Any necessary amendments following the pilot will be discussed and documented with the research team prior to confirming the final moderator script.

Topics included in the moderator script for development with the PAG.
<ul style="list-style-type: none">• The participant's understanding of mobilisation• Their experience of early mobilisation in the ICU• Factors that made mobilisation difficult• Factors that ensured mobilisation was carried out• Were experiences of mobilisation influenced by different health professionals/teams e.g. nurses, physiotherapists, doctors• What were the type of activities e.g. in-bed or out of bed activities

- What factors would be considered as important in carrying out mobilisation and/or the experience

Table 1.

Prior to formal data collection, participants will be emailed information including instructions on entering the password protected Microsoft Teams account, using Microsoft Teams on mobile, laptop or computer devices, privacy settings and expectations for participation including length time of focus group participation. Data collection will cease where sufficient content/data saturation is jointly agreed upon by the research team. Audio-recordings will be simultaneously transcribed verbatim using the [otter.ai program](#), an application compatible with Microsoft Teams. Transcriptions will be reviewed by the moderators and further refined if necessary whilst repeatedly listening back to the original recordings. This will incur a subscription cost of \$12.99 per month in which a moderator will cover. All audio-recordings will be destroyed following the transcription and member check approval. All transcribed data will be anonymised and stored on the St. George's University H:Drive account belonging to a moderator as per [SGREC](#) recommendations.

CONFIDENTIALITY AND DATA STORAGE

Data storage will be in line with the UK Data Protection Act (2018) and [SGREC](#). Data collection will be carried out in the United Kingdom (UK) using an exclusive Microsoft Teams account. Data collection carried out on [Microsoft Teams is compliant with the UK General Data Protection Regulation](#) and SGREC. All data will be stored on the St. George's University H:Drive private account for only the corresponding author to access in accordance with SGREC recommendations. Microsoft Teams allows for privacy settings to be set by the account holder. Entry to focus groups sessions for participants will be via the waiting room feature where only the host can identify and allow access for participants. The researcher will email information to all consenting participants' information that will include details on withdrawing from the study electronically, maintaining confidentiality of other participants' information and utilising Microsoft Teams during focus group discussions.

Recordings will be anonymised following member check approval of transcriptions and identifiable information will be removed prior to data analysis following the Medical Research Council Guidelines and

the General Data Protection Regulation six principles for anonymising data (MRC, 2018; Voigt and von dem Bussche, 2017). All recordings will be destroyed following member check approval of transcriptions. All emails will be deleted immediately. In the case where participants have provided consent to be contacted for future information of the findings of the study and/or future research, their emails will be stored on a secure password-protected NHS email account belonging to the corresponding author for up to five years as per SGREC recommendations.

PATIENT AND PUBLIC INVOLVEMENT (PPI)

PPI ensures relevance and effectiveness of research (Grotz, Ledgard and Poland, 2020). This study aims to include PPI throughout the research process and members of the public as part of the research team as per the NIHR Involve Framework (Hickey, 2020). In accordance with the National Standards for Public Involvement, a public advisory group (PAG) comprising of patients with a lived experience of delirium will be involved to help inform participant recruitment, co-production of a focus group interview script, participant questionnaire, data analysis and dissemination (National Institute for Health Research, 2020). Ethical considerations for PPI throughout the research process will be addressed with guidance from the ethically conscious standards for PPI at the design stage of healthcare research (Pandya-Wood, Barron and Elliott, 2017). Research ethical approval is not a requirement for PPI as per the Health Research Authority Guidance (2020). The research team will apply for charitable funding for PPI, with anticipation of demonstrating respect for service users' time given in contribution to help inform the early design of this study. The cost for PPI activities will be calculated using the [NIHR INVOLVE Budgeting Tool](#), (National Institute for Health Research, 2013). This study is not eligible for the Public Involvement Fund provided by the Research and Development Service London.

DATA ANALYSIS, TRUSTWORTHINESS AND RIGOR

Once all data have been transcribed participants will be consulted to check transcripts for accuracy. Framework analysis incorporating thematic methodology following Ward et al., (2013), Braun and Clarke (2006, 2014), will be carried out by two focus group moderators who will be familiar with the data. Framework analysis allows coding of the data in relation to a specific research question. Thematic

methodology using an experientialist/realist method will report on experiences, meanings and the reality of the participants following focus group discussions. Themes will be uncovered utilising a semantic level of thematic identification. This process will allow description and summarisation of the data, to attempt theorising significant patterns and meanings that can be applied into a wider context. Bias will be accounted for by the moderators' using reflexivity and repeated re-reading of transcripts throughout the analytical process to ensure rigour and appropriate interpretation of themes. Trustworthiness will be demonstrated by completion of a documented audit trail for the stages of development of the themes and sub-themes and the process reviewed by the third moderator who will be familiar with the data (Ward, et al., 2013). Themes identified will be analysed and critiqued by the research team to attain agreement. The themes or patterns identified will inform the co-produced recommendations of this study. No software will be utilised for the process of data analysis.

ASSESSMENT AND MANAGEMENT OF RISK

All participants and PPI will be notified of their ability to withdraw at any point of the research process where there may be any concerns regarding distress over their previous and/or current experience(s) of ICU-delirium. This will be re-iterated throughout the research process from recruitment to dissemination using different methods such as participant information sheets and verbally prior to focus groups. Furthermore, the moderators of the focus groups will actively ensure sensitivity towards participants demonstrating potential signs of distress during data collection and PPI liaison. The moderator scripts will incorporate appropriate language through consultation with the PAG and the PPI representative on the research team to support participant psychological and emotional vulnerabilities. Furthermore, follow-up will be offered to participants who leave the focus group discussions for unstated reasons to check on the participant's wellbeing. The research team members will be made aware of support available if any content is found to cause distress. The ICUSteps Charity has agreed to provide support and their details will be signposted on patient information sheets.

AMENDMENTS

Approval for amendments will be sought where appropriate. Where approved amendments have been made following publication and SGREC registration of this protocol, we will ensure these are clearly communicated and referred to in the final publication. Furthermore, the research team will ensure all amendments are clearly documented throughout each stage of the research process. The Chief Investigator will be responsible for overseeing and reporting amendments throughout each stage of the research process.

PROTOCOL COMPLIANCE

The research team will follow St. George's University of London Research Ethics Committee (SGREC) guidance on obtaining protocol compliance. We recognise accidental deviations are possible therefore we will ensure these are clearly and accurately documented using the relevant forms. In the case of any such events the Chief Investigator of the study will be notified immediately. We acknowledge that any frequently occurring deviations of the protocol are not acceptable and are classified as a serious breach (Health Research Authority, 2017).

FINANCE AND FUNDING

This qualitative study is independent research supported by the National Institute for Health Research HEE/NIHR ICA Programme Pre-doctoral Clinical Academic Fellowship, NIHR301174. The views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health and Social Care.

COSTINGS

Subscription to the otta.ai transcription program on Microsoft Teams will cost \$12.99 per month in which a moderator will privately cover.

ETHICS AND DISSEMINATION

Ethical approval will be administered through the St. George's University Research Ethics Committee (SGREC) prior to commencing the study. Ethical considerations concerning internet-mediated research will be guided by the Association of Internet Researchers (Franzke, et al., 2020).

This study aims to demonstrate transparency, integrity and accessibility throughout the research process and in publication to enable replication of research methods. We aim to maximise accessibility for researchers, service users and the public by disseminating our findings through high quality peer-reviewed publication and conferences. The PAG will support the dissemination of the research findings to the patient support centres of participant recruitment and the participants themselves. Furthermore, we will pursue co-produced publication concerning public engagement in research.

ACKNOWLEDGEMENTS

None.

CONFLICTS OF INTEREST

None.

AUTHOR CONTRIBUTIONS

The order of authorship is in accordance with the International Committee of Medical Editors recommendations (International Committee of Medical Journal Editors, 2017). All authors read, provided feedback and approved the final manuscript for the qualitative research protocol.

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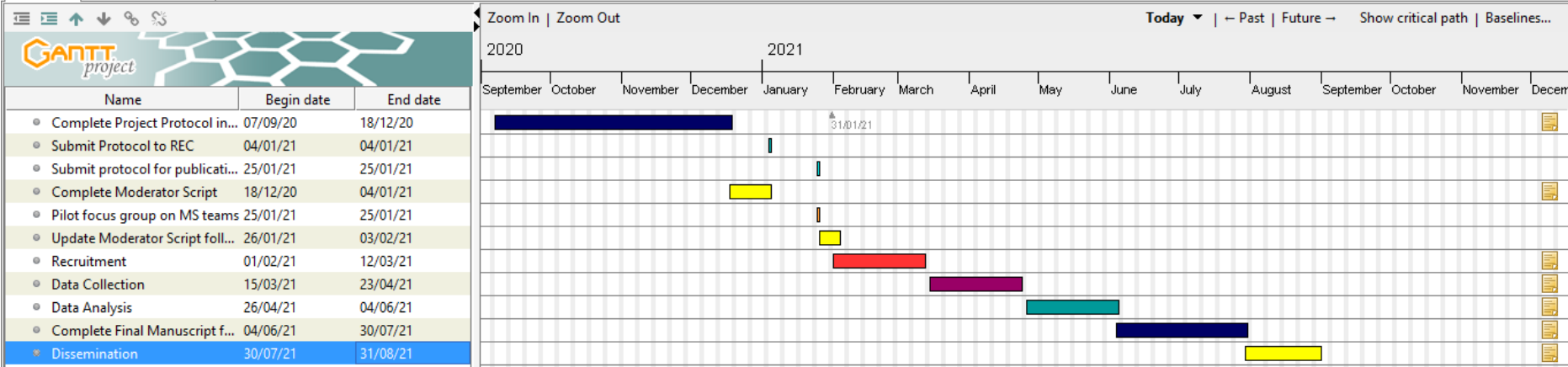
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APPENDIX A

Project timeline



Topics included in the moderator script for development with the PAG.
<ul style="list-style-type: none">• The participant's understanding of mobilisation• Their experience of early mobilisation in the ICU• Factors that made mobilisation difficult• Factors that ensured mobilisation was carried out• Were experiences of mobilisation influenced by different health professionals/teams e.g. nurses, physiotherapists, doctors• What were the type of activities e.g. in-bed or out of bed activities• What factors would be considered as important in carrying out mobilisation and/or the experience

Table 1.