Efficient / innovative delivery of NIHR research – 2022 Projects

Final report

Development and validation of an online version of a new generic modular resource-use measure for RCTs

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1) Title of Project

Development and validation of an online version of a new generic modular resource-use measure for RCTs

2) Abstract

In trial-based economic evaluations, self-report resource-use data has historically been collected in questionnaires which are developed for each new trial with testing rare prior to implementation. In this project, we have developed and tested the electronic version of new standardised, generic modular RUM (ModRUM) in REDCap. eModRUM can be used to collect information on health care, social care, informal care and aids/adaptations. Two versions of each module were developed, allowing trialists and health economists flexibility to collect more detailed information on pertinent resources. eModRUM was developed in REDCap with input from a public advisory group. Qualitative interviews with members of the public were conducted to test the content validity and acceptability. Further work will be undertaken to develop eModRUM in alternate electronic data capture systems, so that it is available for use in trials led by clinical trials units across the United Kingdom.

3) Introduction

In randomised controlled trials (RCTs), data on resource use are commonly collected by participant-report resource-use measures (RUMs) that are developed on a trial-by-trial basis without validation (1). This approach is sub-optimal as a lack of standardisation inhibits comparability of results across RCTs, while the lack of prior testing means RUMs may not be comprehensible or acceptable to trial participants, nor provide valid results. Developing new instruments for each new trial also represents an inefficient use of time. To overcome these issues, in a recently completed MRC HTMR-funded PhD project (undertaken by KG), the

healthcare module of a new standardised, generic modular RUM (ModRUM) was developed and tested (2, 3).

Candidate items were identified in a Delphi study with health economists (4). Items were formulated into ModRUM and measurement properties were tested. Qualitative interviews and piloting with health economists provided evidence of content and face validity, and suitability for costing purposes in economic evaluations. Cognitive interviews and piloting with patients recruited from primary care provided evidence of content validity, construct and criterion validity, feasibility and acceptability (2, 3). The core healthcare module contains 11 questions and can be completed in approximately 5 minutes (see bristol.ac.uk/modrum, for a sample version). It was considered by NIHR-funded health economists to be applicable to estimate healthcare costs across a wide range of RCTs. Further testing of the healthcare module is underway in several RCTs. In an NIHR RfPB project, social care, informal care and aids/adaptations modules have also been developed and tested.

ModRUM provides a generic, modular and validated method for collecting self-report data on paper. The pandemic accelerated the use of electronic data capture (EDC) from trial participants, increasing the need for a validated electronic RUM, which would increase efficiency. EDC in trials offers many advantages, including potential cost and environmental savings. For participants, burden can be reduced by utilising skip logic so that participants only see relevant questions and by providing more detail to enhance comprehensibility. Burden can also be reduced as drop-down lists can replace free text fields, which also allows for more efficient analysis. Missing data can be minimised by utilising reminders and/or enforcing responses. EDC also eliminates the need for data entry, where errors can occur, and validation is needed. For PROMs, it has been asserted that data collected in electronic versions should be equivalent or superior to data collected in paper versions (5), with a subsequent review indicating equivalence (6). When the content of a PROM has not substantially changed, evaluation of an EDC version can be limited to cognitive and usability testing (5).

The overall aim of this project was to develop and test an electronic version of ModRUM. The objectives were to:

1. develop electronic versions of four ModRUM modules, (healthcare, social care, informal care, and aids and adaptations) in REDCap,
2. test the acceptability and validity of the electronic modules,
3. create a design specification so that ModRUM can be developed in other EDCs,
4. develop the tested version in alternative EDC systems used by UKCRC-registered CTUs.

4) Methods

Development of electronic ModRUM (eModRUM) in REDCap

While a variety of EDC systems are available and used across CTUs for data capture (e.g. REDCap, OpenClinica, MACRO), REDCap is popular because it is a secure web-based application specifically designed for clinical research and widely available (7). All ModRUM modules were developed in REDCap. Alpha testing was conducted by the BTC database team. Following this a test plan was devised to confirm the system functions as designed, including checking that eModRUM works on a range of devices (e.g. smart phones, tablets). A public advisory group (PAG) was formed, and they were asked to review the modules, which included testing of links to access eModRUM and functionality (e.g. ability to edit answers, skip logic), prior to providing feedback at a public advisory group meeting. Following amendments, eModRUM was migrated to the production REDCap Servers.

Qualitative interviews to assess acceptability and validity

As recommended for the assessment of content validity and implemented in the development of the paper version of ModRUM, cognitive interviews including a think-aloud exercise were conducted with a sample of the general population to assess acceptability and validity and provide feedback on the design (2, 8). A range sources were contacted to advertise the study. To increase diversity in the sample, interested individuals were be asked to complete a reply form (prepared on www.onlinesurveys.ac.uk), where they provided contact details, sociodemographic details (including age group, sex, ethnic group, residential status, rurality), and information on their health status, and use of social care and informal care. Approximately 25 interviews were planned with a researcher with training and experience of qualitative interviews. Interviews could take place either face-to-face or online, dependent on participant and researcher preferences. 'Think-aloud' interviews were

conducted and respondents were asked to complete the questionnaire while verbalising their thought processes (9). By listening to these thought processes, the researcher had the opportunity to identify issues during instrument completion. Following completion of eModRUM, retrospective verbal probing was used to explore areas where the participant experienced difficulty, and areas of interest to the research team from the pre-defined topic guide. The latter focused on the usability of eModRUM, and areas for improvement.

Participants completed eModRUM on an electronic device of their choice (e.g. smart phone, laptop). The option of using a tablet provided by the researcher was available for in-person interview. Interviews were audio-recorded and transcribed verbatim. Analysis of transcripts first involves using a standardised classification scheme based on Tourangeau's survey response model to identify errors during the four stages of the cognitive process of answering questions (10). Second, qualitative analysis of transcripts in NVivo software, draws upon techniques of constant comparison to identify emerging themes (11). Interviews are conducted in rounds, with interviews, analysis and revisions to eModRUM conducted simultaneously to allow revisions to be tested in future interviews. Based on the interview findings, the final version of eModRUM will be developed, along with an eModRUM user guide and a data specification document, which will describe how ModRUM can be consistently developed in other EDC systems (e.g. instructions on data types and dependency).

Development of eModRUM in other EDC systems

While REDCap is one of the most commonly used EDC systems among CTUs, to make eModRUM widely available for use across CTUs, we will collaborate with staff at other CTUs in the network to develop eModRUM in the most commonly used EDC systems. Two EDC systems will be identified from a recent survey of CTUs which was conducted to identify what EDC systems CTUs use. Collaborators from the UKCRC IT group will facilitate introductions with UKCRC-based EDC system user groups. From these groups, we will seek collaborators to use the eModRUM design specification (developed based on the REDCap design) to develop ModRUM in another system. Collaborators will be able to provide feedback, and BTC-based researchers will test the systems with them. Once finalised,

collaborators will make their version of eModRUM available, so that it can be used by other CTUs.

5) Results and Conclusion

Four ModRUM modules, covering health care, social care, informal care and aids/adaptations, were developed in REDCap using an iterative approach. Each module has two versions, a core 'short' version and a depth 'long' version. The core versions include no free-text fields, and provide the minimal information likely to be required to value the resources for an economic evaluation. The depth versions include questions that require more detail from the respondent to enable more precise valuation.

Formatting of response options was considered first, with options including buttons and drop-down fields. Feedback was sought from the research team and public advisors. Buttons were the preferred choice, predominantly for the ease of selecting a number. Following this, all modules were developed in REDCap. The modules were initially reviewed by the research team, edits were made iteratively until the team agreed that they were ready for external feedback. Rather than simply replicate the paper version of ModRUM in REDCap, the research team and developer considered multiple options for each type of question to make best use of REDCap functionality and reduce respondent burden.

Four people were recruited to take part in a public advisory group. Prior to the PAG meeting, they were sent both versions of eModRUM and tested their functionality. At the meeting on July 12th, 2023, PAG members provided feedback on response option format, skip logic, enforced answers, instructions, terminology and content. Based on the feedback, changes included:

- filter questions were added to the healthcare module to make use of skip logic and reduce the number of questions displayed when they were not required,
- enforcement was added to 'top-level' questions,
- drop down lists with common resources were added to tables (e.g. outpatient clinic type). The lists were formed by reviewing data in the National Schedule of NHS costs (12).

Some potential issues raised by the PAG group did not lead to changes to eModRUM, but instead were flagged as things to explore in qualitative interviews. One issue raised was the terminology used in the informal care module; however, there were mixed views from the PAG on whether it should be changed. Another was whether participants will answer 'zero' in tables when they have not used resources.

Invitations to express an interest in participating in a qualitative interview were sent via People in Health West of England. To date, 19 people have expressed an interest in taking part in an interview, three interviews have been conducted, with more scheduled. Participants have provided feedback on the length, content, appearance and functionality of eModRUM. The transcripts will be coded for errors and analysed qualitatively before edits are made and tested in further interviews.

Once development and testing are complete, eModRUM will be a valuable resource that can be used in HTA-funded RCTs to collect resource-use data. Using eModRUM within trials will improve efficiency, by reducing the need to develop a new resource-use measure for each new trial. Thorough testing of ModRUM prior to administration in trials should reduce participant burden and improve data quality.

6) Dissemination

Once the REDCap version is finalised, we plan to collaborate with the UKCRC IT group and UKCRC-based EDC system user groups to develop eModRUM in other EDC systems. Working with these groups will create awareness of eModRUM among CTUs, and during the meetings we will highlight the advantages of using a generic survey both for researchers and research participants.

We anticipate final edits to eModRUM will be complete in early 2024. eModRUM will then be made freely available for non-commercial use via the dedicated ModRUM webpage (www.bristol.ac.uk/modrum). We will advertise eModRUM via an email to UKCRC-registered CTUs, via the DIRUM website (www.dirum.org), the JiscMail health economics mailing list and the NIHR TMRP Health Economics Working Group. To reach CTU-based researchers and the wider NIHR research community, including health economists and trialists, we will

submit an abstract to the International Clinical Trials Methodology Conference 2025. We will also submit a paper to an open-access peer-reviewed publication.

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9) Appendices

Not applicable.

10) Conflict of interest declaration

All authors' declare no competing interests.

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