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Developing and evaluating multimedia information resources to improve engagement of children, adolescents and their parents with trials

Submission date
23/08/2016

Recruitment status
No longer recruiting

Registration date
24/08/2016

Overall study status
Completed

Last Edited
27/12/2023

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Patients are usually informed about clinical trials using printed participant information sheets, which have been much criticised for being too long and technical to inform patients adequately. Multimedia information resources (MMIs) are computer-based and include text, audio, video and animations. The user can choose which sections to read and view, and in which order. It may be possible for the user to post questions on the MMI, so making it interactive. Studies with adult patients suggest that MMIs may work, but they have not been tested with younger patients. The aim of this study is to compare three methods of providing information to potential trial participants: participant information sheet alone, participant information sheet plus an MMI, or the MMI alone.

Who can participate?
Children and adolescents aged 6-17 with long-term health conditions

What does the study involve?
The study has two phases. In the first phase two MMIs are developed, one for parents and adolescents, and another (less complex) for younger children and their parents. The two MMIs mostly feature content that applies to all trials and some content that applies to the specific trial that the patient is being asked to consider. This content reflects the content found in a traditional participant information sheet. Group discussions are conducted with children and adolescents, parents and clinical staff, to identify preferences for content, tone, style and delivery. The MMIs are developed before returning to the groups for more discussion. The MMIs are then revised as required. The MMIs are then tested for people's ability to find and understand the content by conducting individual interviews with children, adolescents and parents. After a round of 20 people on each MMI, they are revised and tested again as necessary. In the second phase the effects of the MMIs are evaluated in six different healthcare trials involving children and adolescents. When being asked to take part in the trials, potential trial participants are randomly allocated to see the standard written trial information, the standard

written information plus an MMI, or the MMI alone. The study assesses participants' decisions, how sure they are that they have made the right decision, how satisfied they were with the process, and also looks at rates of recruitment to the trials and how long people stay on them.

What are the possible benefits and risks of participating?
Possible benefits are that participants may be able to make a more informed decision about trial participation as they will receive additional information in a more accessible and engaging format. No risks identified by participating other than loss of time for those participants who receive the MMI and participant information sheet as a result of receiving additional information about the trial available.

Where is the study run from?
University of York (UK)

When is the study starting and how long is it expected to run for?
March 2016 to November 2021 (updated 20/04/2021, previously: April 2021 (updated 08/07 /2020, previously: December 2018))

Who is funding the study?
Health Services and Delivery Research Programme (UK)

Who is the main contact?
Dr Jackie Martin-Kerry
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
HS&DR 14/21/21

Study information

Scientific Title
Trials Engagement in Children and Adolescents (TRECA): a randomised controlled trial

Acronym
TRECA

Study objectives
The study is designed to develop and evaluate multimedia information resources (MMI) to improve the quality of decision making about recruitment to clinical trials involving children and adolescents with long-term health conditions. Participant information sheets are often criticised for being long and difficult to read and TRECA is investigating whether participant information provided in a multimedia format will increase recruitment of children and adolescents into healthcare trials and to also look at the effect on decision making and retention in trials.

This study will compare two methods of providing information to potential trial participants: either participant information sheet alone or participant information sheet plus MMI resource, to determine effects on recruitment, retention rates and quality of decision making.

Updated 04/05/2017:
This study will compare three methods of providing information to potential trial participants: the participant information sheet alone, the participant information sheet plus an MMI or the MMI alone, to determine effects on recruitment, retention rates and quality of decision making.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Phase 1 qualitative study: Yorkshire and The Humber Research Ethics Committee, 13/04/2016, ref: 16/YH/0158; IRAS ID 195396
2. Phase 1 user testing study: Yorkshire & The Humber – Bradford Leeds Research Ethics Committee, 02/09/2016, ref: 16/YH/0387; IRAS ID 213557
3. Phase 2: Yorkshire & The Humber – Bradford Leeds Research Ethics Committee, 29/03/2017, ref: 17/YH/0082; IRAS ID 212761

Primary study design
Interventional

Study design
Multi-centre randomised controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Long-term health conditions

Interventions
Current interventions as of 04/05/2017:
1. Intervention group 1 (receives information about the trial by MMI plus standard participant information sheet)
2. Intervention group 2 (receives information about the trial by MMI alone)

3. Control group (standard participant information sheet only): receives trial information only through standard participant information sheet

Previous interventions:
1. Intervention group (receives information about the trial by MMI plus standard participant information sheet)
2. Control group (standard participant information sheet only): receives trial information only through standard participant information sheet

Intervention Type
Other

Primary outcome(s)
Trial recruitment rates: the proportion of patients who agree to participate in the host trial, from the total number of patients approached, for each arm of the embedded trial at baseline.

Key secondary outcome(s)
1. Rates of retention of children and adolescents in the six host trials, measured by obtaining data on the number and timing of drop outs from each host trial at end/completion date of each of the six trials.
2. Quality of decision-making by respondents. The quality of decision-making by participants is a subjective outcome measure and will be measured at baseline through the completion of a quality of decision-making scale by children, adolescents and parents (as relevant).

Completion date
30/11/2021

Eligibility

Key inclusion criteria
1. Paediatric patients who are aged between 6-17 years who have a long-term health condition and are eligible to be recruited into a host clinical trial
2. Both female and male

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Years

Upper age limit
17 Years

Sex

All

Total final enrolment
1906

Key exclusion criteria
1. Paediatric patients who cannot participate in informed consent due to being too young (less than 6 years) or due to intellectual disability
2. Paediatric patients or their parents who do not speak English

Date of first enrolment
01/03/2017

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name

Health Services and Delivery Research Programme

Alternative Name(s)
Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the TRECA research team. All data requests will be managed according to the Department of Health Sciences, University of York processes and procedures. The TRECA research team may be contacted at: treca@york.ac.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2023	27/12/2023	Yes	No
Protocol article	protocol	08/06/2017		Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No
HRA research summary			26/07/2023	No	No
Interim results article	Qualitative results	09/01/2019	12/02/2020	Yes	No
Interim results article	Results from BAMP host trial	06/07/2021	14/11/2022	Yes	No
Interim results article	Results from FORCE host trial	13/07/2022	14/11/2022	Yes	No
Interim results article	Results from Thermic-3 host trial	21/03/2022	14/11/2022	Yes	No
Other publications	Challenges encountered in embedding MMIs	01/12/2019	16/03/2021	Yes	No

Other publications	PPI work	01/02/2020	16/03/2021	Yes	No
Other publications	User testing	01/09/2019	16/03/2021	Yes	No
Other publications	User testing	01/11/2018	16/03/2021	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes