ISRCTN39238984 https://doi.org/10.1186/ISRCTN39238984

Power Up for Parents: a pilot study

Submission date
04/07/2018

Recruitment status
No longer recruiting

Registration date
04/07/2018

Overall study status
Completed

Last Edited
03/03/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The aim of this study is to develop and evaluate a mobile app (called Power Up for parents) to promote parent's involvement in shared decision making in Child and Adolescent Mental Health Services (CAMHS). The results of this study may be used to improve the shared decision making approaches taken by clinicians in CAMHS and inform the level of support parents need when choosing to be involved in the shared decision making process. The study will show whether a larger study is feasible and provide early evidence for the app's effectiveness.

Who can participate?
Parents/primary caregivers of at least one young person accessing mental health services

What does the study involve?
The study consists of two stages, the development stage (Stage 1) and the pilot testing stage (Stage 2). During the development stage, focus groups and interviews with parents and clinicians are conducted and the interview topic guide aims to capture parents' experience of making child mental health decisions, coping strategies used, preferences for involvement in shared decision making, decision support needs, and situations within which the app can be best used. During the pilot testing stage, parents are randomly allocated to use either Version 1 of Power Up for Parents, Version 2 of Power Up for Parents, or to not use the app but to complete the same questionnaires and receive treatment as usual. The acceptability, usefulness, usability, and preliminary effectiveness of Power Up for parents is assessed, as well as the feasibility of carrying out a full study. Measurements assess shared decision-making, usefulness and acceptability, and are completed by parents/caregivers at the start of the study and at three months follow up or case closure/discharge (whichever comes first).

What are the possible benefits and risks of participating?
While there is no guaranteed benefit in taking part in this study, one advantage is that participants will get to help shape an app that caregivers, clinicians, and children may use in the future. Most participants find taking part in research rewarding, as they contribute to the development of knowledge that may benefit themselves and others. There are no known risks to taking part in these interviews or focus groups. If any risks become known during the study, participants will be informed straight away. Since the main purpose is to obtain participants'

feedback, questions may require participants to explore sensitive topics. However, if participants experience discomfort, they will be treated with compassion and signposted to further help if needed.

Where is the study run from?
1. University College London (UK)
2. Anna Freud National Centre for Children & Families (UK)
3. Tavistock & Portman NHS Foundation Trust (UK)
4. Barnet, Enfield & Haringey Mental Health NHS Trust (UK)
5. Central & North West London NHS Foundation Trust (UK)
6. North East London NHS Foundation Trust (UK)
7. West London Mental Health NHS Trust (UK)
8. North West Boroughs HealthCare NHS Foundation Trust (UK)
9. Cheshire & Wirral Partnership NHS Foundation Trust (UK)
10. Lancashire Care NHS Foundation Trust (UK)
11. South West London & St George's Mental Health NHS Trust (UK)
12. East London NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2018 to October 2019

Who is funding the study?
Horizon 2020

Who is the main contact?
Mr Shaun Liverpool

Contact information

Type(s)
Scientific

Contact name
Mr Shaun Liverpool

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Contact details
8 Hunter St
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17/1904

Study information

Scientific Title
Power Up for Parents: a pilot study promoting parental involvement in shared decision making through technology

Study objectives
The primary research objective of this study is to investigate whether an evidence-based mobile application co-designed with parents can promote SDM for parents of children accessing CAMHS?

The following secondary research questions will be addressed:
1. Is the app accepted by and useful for the chosen population?
2. What emotional factors impact the shared decision-making process?
3. Is it feasible to conduct a full RCT?
4. What are the initial findings for the effectiveness of Power Up for Parents?

Ethics approval required
Old ethics approval format

Ethics approval(s)
London- Surrey Research Ethics Committee, 05/06/2018, REC ref: 18/LO/0978

Study design
Pilot controlled multi-site trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Parents of children with mental health challenges

Interventions

The intervention (Power Up for Parents) will be co-designed with parents of children accessing mental health services to ensure it is user-friendly and useful to the chosen population. By taking this approach, it is less likely that that the content will cause any distress and it will be received as a support tool to allow parents to be part of the decision making process for their child. Links to additional support will also be available to parents via Power Up for Parents.

The app will allow parents to track their decision making, explore options by being signposted to further information, ability to document feelings and thoughts and receive brief emotional support by way of emotional regulation or acceptance, or self-compassion mechanisms. The content will be screened by various parent groups and professionals and tested with alpha and beta groups before being used in the pilot study.

The overall structure of the app's content will be as follows:

My Goal
This can be used in sessions/meetings or between sessions/meetings to record goals and plans as they are discussed with healthcare professionals and/or the child. This will allow users to plan and record any questions or concerns they have and can address it at the next session/meeting. Expectations, experiences, goals, reflections can all be recorded here.

My Journey
This section allows parents to record information about their child that may be affecting the decision processes. The parent can decide to share this content with child and/or clinician and can be used during and within sessions to keep track of the decision-making journey from user readiness to outcomes. This space will allow parents to record benefits and risks of each available option and explore other resources to support such information.

My Decision
This section will give users access to information about options in service and act as a Decision Aid so users can consider treatment options, benefits and risks of each option, track decisions, and record where more information or support is needed. Additionally, as this is a triad relationship, users will be prompted to seek preferences from clinicians and child during this process.

My Decision Support
This section will host the user's help library and provide access to information about psychological and emotional support services. Users will be able to access brief emotional support (occasional emotional acceptance prompts/mindfulness), track feelings about decisions and record where additional emotional needs and support is required.

Site Recruitment
Child and Adolescent Mental Health Services (CAMHS) will be selected from within the London Borough and a key contact person will be identified at each site. The contact person will circulate information about the study to all clinicians and then clinician will be invited to an information session where they will receive information packages. Clinicians will then review their work loads and identify suitable participants already accessing their services based on the inclusion/exclusion criteria. This will be a transparent process where clinicians will sift through their patient list and select suitable participants.

Clinicians will then inquire if the highlighted names are interested in the study and add them to a database of interested participants. The key contact will then provide the list of interested

participants from the database and respective contact details. The participants will then be contacted by the researcher to be given more information and invited to participate in the study.

Additionally, researchers will attend services and distribute information sheets and recruit onsite volunteer participants. Parent support groups at the CAMHS services will also be approached and parents given the opportunity to volunteer as a participant after information sessions. Also, our main contact at the service will share information about the study through opportunistic participant identification. These forms of identification will be guided and informed by PPI participants (Parent Networks) whose expertise will be sort to inform the recruitment process.

Development Stage
This stage will involve semi-structured interviews and focus groups to gather qualitative data for the content and design of the Power Up for parent's app. Participants (N= 50) will have been recruited by either of the above mentioned routes at the various sites (i.e. parent groups, recommendations from clinicians, advertisements or researchers attending services). All participants will be given information sheets and consent forms in advance of the interviews and focus groups. However, consent forms will be signed in the presence of the research on the day of the interview. At this stage, an existing prototype of power up will be shown and suggestions for content and prototype upgrades will be gathered. Focus groups are expected to last up to 1 hour and 30 minutes and interviews lasts up to 1 hour.
In the focus groups and interviews, participants will review the current prototype of power up (paper and digital versions) on materials supplied by the researcher. Feedback on all aspects of the prototype will be solicited and questions about the additional support needs and recommendations will asked. In addition, usefulness of the intervention and preference for modality will be sought. At the end of the focus groups and interviews participants will be debriefed and advised to contact researchers with any further questions or suggestions via our details previously given on information sheets.Convenient sampling will be used for obtain clinicians views for input into the app content and design.

Pilot Testing Stage
This stage involves re-inviting previous participants and obtaining informed consent from additional participants, recruited in identical routes as the development stage, to use the prototype and give feedback on usefulness, usability, acceptability and inform effectiveness. Up to 90 parents will be invited to participate in this stage with approximately 30 being allocated Version 1 of Power Up, another 30 being allocated Version 2 and the remaining 30 as the control receiving no app but subject to same battery of questionnaires and treatment as usual. Participants will be assigned to intervention or control group based on the site they have been recruited from to avoid contamination. Again, informed consent will be signed and information sheets with information on the testing phase will be shared. Depending on date recruited, participants will have as long as they need to decide whether to take part in the study. Participants will meet with the researcher at a time convenient to them to complete a battery of baseline questionnaires which consists of shared decision making measures,experience of service, and decisional conflict measures. Depending on which group the participants fall into, they will receive help to download the power up for parents app and a guided tour of the app. The parent will then go away and use the app as much as they need to. Participants will meet with the researcher for follow-up at 3 month after or discharge (whichever comes first) to complete same questionnaires as baseline and additional measures to capture acceptability and usability.
Clinicians will also complete the dyadic OPTION scale to measure shared decision making from their perspective.It may also be important for clinicians to report any changes in length of appointments or missed appointments and improvements in child's mental health.

At the end of the pilot testing phase, all participants will share opinions on the study and more specifically on the intervention use and will then be debriefed and thanked for their participation.

Intervention Type
Other

Primary outcome measure
Shared decision making measured by change in Paediatric SDM Questionnaire (PSDM-Q-Parent) scores, Dyadic OPTION scale (Clinician) (STAI), Decisional Conflict Scale for Paediatrics (CSP-P), and Experience of Service Questionnaire (ESQ) at baseline (during initial sessions) and 3 months

Secondary outcome measures
Anxiety levels measured by Spielberger State Anxiety Inventory Form at baseline (during initial sessions) and 3 months

Overall study start date
09/01/2018

Completion date
01/10/2019

Eligibility

Key inclusion criteria
Preliminary inclusion criteria for parents are as follows:
1. Over the age of 18
2. No known diagnosed mental health issues
3. Ability to speak and understand English
4. Parent/primary caregiver of at least 1 young person accessing mental health services

Participant type(s)
Carer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Total Planned Sample Size: 140; UK Sample Size: 140

Key exclusion criteria
1. Concurrent and/or any involvement in other research that is likely to interfere with the intervention (determined by the researcher)
2. Adolescent mothers

3. Parents or guardians in cases where the child/young person is being treated under a section of the Mental Health Act

Date of first enrolment
01/07/2018

Date of final enrolment
01/10/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
Gower Street
Bloomsbury
London
United Kingdom
WC1E 6BT

Study participating centre
Anna Freud National Centre for Children & Families
Jordan House
47 Brunswick Place
London
United Kingdom
N1 6EB

Study participating centre
Tavistock & Portman NHS Foundation Trust
120 Belsoze Lane
London
United Kingdom
NW3 5BA

Study participating centre
Barnet, Enfield & Haringey Mental Health NHS Trust
St Ann's Hospital
St Ann's Road

London
United Kingdom
N15 3TH

Study participating centre
Central & North West London NHS Foundation Trust
Stephenson House
75 Hampstead Road
London
United Kingdom
NW1 2PL

Study participating centre
North East London NHS Foundation Trust
Trust Head Office
CEME Centre
West Wing
Marsh Way
Essex
United Kingdom
RM13 8GQ

Study participating centre
West London Mental Health NHS Trust
Trust Headquarters
1 Armstrong Way
Southall
United Kingdom
UB2 4SD

Study participating centre
North West Boroughs HealthCare NHS Foundation Trust
Hollins Park Hospital
Hollins Lane
Winwick
Warrington
Cheshire
United Kingdom
WA2 8WA

Study participating centre

Cheshire & Wirral Partnership NHS Foundation Trust
Trust Headquarters Redesmere
Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1BQ

Study participating centre
Lancashire Care NHS Foundation Trust
Sceptre Point
Sceptre Way
Bamber Bridge
Preston
Lancashire
United Kingdom
PR5 6AW

Study participating centre
South West London & St George's Mental Health NHS Trust
Springfield Hospital
61 Glenburnie Road
London
United Kingdom
SW17 7DJ

Study participating centre
East London NHS Foundation Trust
Trust HQ
9 Alie Street
London
United Kingdom
E1 8DE

Sponsor information

Organisation
University College London

Sponsor details

UCL, 1st Floor Maple House
149 Tottenham Court Road
London
England
United Kingdom
W1T 7NF

Sponsor type
University/education

Website
http://ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Horizon 2020 Marie Sklodowska-Curie Action (MSCA) Grant number 722561

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Study protocol will be available after it is published (open-access) in a peer-reviewed journal. Findings of both phases of this study will be disseminated through publications in peer-reviewed journals, form part of the researcher's PhD thesis, an internal report, and conference presentations. Results will also be published on the UCL, AFC and NHS Hospital/CAMHS websites.

Intention to publish date
02/01/2020

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/08/2019	16/08/2019	Yes	No
Results article	results	02/03/2021	03/03/2021	Yes	No
HRA research summary			28/06/2023	No	No