A feasibility trial of Power Up

Submission date	Recruitment status	[X] Prospectively registered		
02/11/2016	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
07/11/2016	Completed	Results		
Last Edited	Condition category	Individual participant data		
10/01/2018	Mental and Behavioural Disorders	Record updated in last year		

Plain English summary of protocol

Background and study aims

Young people with mental health difficulties need support to ensure their voice is heard during therapy. Evidence suggests that young people want to be actively involved in their care and in decisions about their treatment (shared decision making), but this does not always happen in practice. There are a number of barriers to young people being involved in shared decision making in mental health services. The process of shared decision making is sometimes perceived as too time consuming by clinicians and there is also a lack of age appropriate resources to support the process. Many young people already use technology as an informal complement to treatment. More research is required to better understand how best to incorporate this type of technology into services. In response to this a smartphone app has been developed, which aims to support young people, aged 11-19, who are in the initial stages of therapy. The Power Up app provides young people with six tools to use within and between sessions with Child and Adolescent Mental Health Services (CAMHS). The aim of these tools is to empower young people to be more actively engaged in their care and decisions about their care by supporting them to record their experiences, questions, opinions and tasks or actions related to their care. The aim of this study is to find out whether it would be feasible and acceptable to conduct a study looking at the effectiveness of Power Up within a CAMHS service.

Who can participate?

Young people (aged 11-19 years) who have recently been referred to a participating CAMHS with emotional difficulties who own a smartphone.

What does the study involve?

The study is made up of two phases. In the first phase of the study, 30 participants are recruited and asked to continue to receive treatment as usual from the CAMHS. At the start of this phase and then three months later, participants complete a number of questionnaires to measure shared decision making, empowerment, patient activation and symptoms of emotional and behavioural difficulties. In the second phase, 30 new participants are recruited and are given access to the Power Up app as well as their usual CAMHS sessions. The Power Up app includes a range of tools to use within and between CAMHS sessions. At the start of the phase and then three months later, participants complete a number of questionnaires to measure shared decision making, empowerment, patient activation and symptoms of emotional and behavioural difficulties.

What are the possible benefits and risks of participating?

There are no guaranteed benefits of taking part. One advantage is that young people will get to help shape a tool that clinicians, young people, and their families may use in future. Most people find taking part in research rewarding, as they contribute to the development of knowledge that may benefit other people in the future. There are no notable risks involved with participating.

Where is the study run from?

- 1. Tavistock and Portman CAMHS (UK)
- 2. Barking and Dagenham CAMHS (UK)
- 3. Tower Hamlets CAMHS (UK)
- 4. Central & North West London CAMHS (UK)
- 5. Barnet, Enfield & Haringey CAMHS (UK)
- 6. West London CAMHS (UK)
- 7. Hackney Children's Social Care

When is the study starting and how long is it expected to run for? September 2015 to March 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Julian Edbrooke
Julian.Edbrooke-Childs@annafreud.org

Contact information

Type(s)

Scientific

Contact name

Dr Julian Edbrooke

Contact details

Anna Freud Centre
4-8 Rodney Street
London
United Kingdom
N1 9JH
+44 (0)20 7443 2275
Julian.Edbrooke-Childs@annafreud.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

A feasibility trial of UCL's Power Up: a smartphone app to support young people to make shared decisions in therapy

Study objectives

The aim of this study is to:

- 1. Develop a smartphone app, in collaboration with young people, parents and clinicians, which aims to support young people's voice in Child and Adolescent Mental Health Services
- 2. Determine whether it is feasible and acceptable to study the effectiveness of Power Up using a cluster controlled trial

Ethics approval required

Old ethics approval format

Ethics approval(s)

Queen Square NRES Committee, 15/06/2016, ref: 16/LO/0891

Study design

Multi-centre feasibility wait-list controlled trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Other

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Specialty: Mental Health, Primary sub-specialty: Anxiety - emotional; UKCRC code/ Disease: Mental Health/ Behavioural and emotional disorders with onset usually occurring in childhood and adolescence

Interventions

Current Interventions (as of 10/01/2018):

The study is formed of two phases. 30 participants are recruited to take part in the first phase (control phase) and 30 are recruited to take part in the second phase (intervention phase).

Control Phase (January 2017 – June 2017): Participants will receive treatment as usual for their presenting emotional difficulties. Participants will complete questionnaires measuring shared decision making, empowerment, activation and symptoms at the point of recruitment and again three months later.

Intervention Phase (June 2017 – December 2017): Participants will use Power Up alongside their CAMHS sessions, where they will receive treatment as usual for their presenting emotional difficulties. Young people will download Power Up and are asked to use the app between and within these sessions to record diary entries, plans, questions, decisions and information about the sessions.

Power Up is an app for young people, aged 11-19, in CAMHS to use independently. The Power Up app will provide young people with six tools to use within and between CAMHS sessions. The objective of these tools is to empower young people to be more actively engaged in their care and decisions about their care by supporting them to record their experiences, questions, opinions and tasks or actions related to their care. Users can enter information into the app using text, audio, video and photos. In 'My Diary', young people can record diary entries expressing their thoughts and feelings on their experiences. In 'My Plans', young people can record step by step plans for achieving goals or tackling difficulties. In 'My Questions', young people can record questions they would like to ask relevant others involved in their care (e.g. their CAMHS clinician), and then record their response. 'My Decisions' is a space for young people to work on decisions using a structured approach; by adding the pros and cons and weighting the importance of each one. Additionally, users will record a list of all the people in their support network, including their CAMHS clinician, in My People when they first download the app. As Power Up users add entries to the app, they will be reminded to consider if they want to talk to any of the individuals in My People about their entry. Finally, the Help and Support tool will signpost young people to other relevant resources giving information and advice. Young people will be able to add their own links and phone numbers to the list. Participants will complete questionnaires measuring shared decision making, empowerment, activation and symptoms at the point of recruitment and again three months later.

Previous Interventions:

The study is formed of two phases. Sixty participants are recruited to take part in the first phase (control phase) and sixty are recruited to take part in the second phase (intervention phase).

Control Phase (September 2016 – February 2017): Participants will receive treatment as usual for their presenting emotional difficulties. Participants will complete questionnaires measuring shared decision making, empowerment, activation and symptoms at the point of recruitment and again three months later.

Intervention Phase (March 2017 – August 2017): Participants will use Power Up alongside their CAMHS sessions, where they will receive treatment as usual for their presenting emotional difficulties. Young people will download Power Up and are asked to use the app between and within these sessions to record diary entries, plans, questions, decisions and information about the sessions.

Power Up is an app for young people, aged 11-19, in CAMHS to use independently. The Power Up app will provide young people with six tools to use within and between CAMHS sessions. The objective of these tools is to empower young people to be more actively engaged in their care and decisions about their care by supporting them to record their experiences, questions, opinions and tasks or actions related to their care. Users can enter information into the app using text, audio, video and photos. In 'My Diary', young people can record diary entries expressing their thoughts and feelings on their experiences. In 'My Plans', young people can record step by step plans for achieving goals or tackling difficulties. In 'My Questions', young

people can record questions they would like to ask relevant others involved in their care (e.g. their CAMHS clinician), and then record their response. 'My Decisions' is a space for young people to work on decisions using a structured approach; by adding the pros and cons and weighting the importance of each one.

Power Up users can choose to 'flag up' the diary entries, plans, questions and decisions which they wish to discuss with relevant others involved in their care. There will also be a space for the young person to record their own notes, tasks or actions from CAMHS appointments in 'My Sessions'. Finally 'My Library' will consist of a list of links, signposting young people to other relevant resources giving information and advice, to which the young person can add. Users of the Power Up app will not be able to digitally share information that they enter. Participants will complete questionnaires measuring shared decision making, empowerment, activation and symptoms at the point of recruitment and again three months later.

Intervention Type

Other

Primary outcome measure

Young people:

Shared decision making is measured using CollaboRATE, Shared Decision Making Questionnaire – 9, and four items of the ESQ (proxy measure) at baseline and 3 months (for each phase).

Clinicians:

Shared decision making in young people is assessed using the Dyadic OPTION Scale at baseline and 3 months (for each phase).

Secondary outcome measures

- 1. Empowerment is measured using the Youth Empowerment Scale Mental Health
- 2. Patient activation is measured using the Patient Activation Scale Mental Health
- 3. Symptoms of emotional difficulties are measured using the Strengths and Difficulties Questionnaire
- 4. Service use is measured using the Client Service Receipt Inventory Children's Version (parent report)
- 5. Number of sessions attended, number of Did Not Attends, type of intervention and type of presenting problems will also be reported by clinicians for each participant at three months

All measures are taken at baseline (during initial sessions) and three months later unless otherwise stated.

Overall study start date

01/09/2015

Completion date

31/03/2018

Eligibility

Kev inclusion criteria

Current inclusion criteria (as of 10/08/2018):

- 1. Recent referral to CAMHS at the point of recruitment
- 2. Aged 11-19 years
- 3. Presenting to CAMHS with emotional difficulties, such as anxiety or depression (Strengths and

Difficulties Questionnaire score of ≥ 7)

- 4. Able to understand English sufficiently to provide informed consent
- 5. Own a smartphone

Previous inclusion criteria:

- 1. Recent referral to CAMHS at the point of recruitment
- 2. Aged 11-19 years
- 3. Presenting to CAMHS with emotional difficulties, such as anxiety or depression (Strengths and Difficulties Questionnaire score of ≥ 7)
- 4. Able to understand English sufficiently to provide informed consent
- 5. Own an iPhone

Participant type(s)

Patient

Age group

Child

Lower age limit

11 Years

Upper age limit

19 Years

Sex

Both

Target number of participants

Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria

Clinician identifies a reason why the young person's vulnerabilities would make them inappropriate to participate

Date of first enrolment

01/01/2017

Date of final enrolment

31/12/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Tavistock and Portman CAMHS

The Tavistock and Portman
NHS Foundation Trust Tavistock Centre
120 Belsize Lane
London
United Kingdom
NW3 5BA

Study participating centre Barking and Dagenham CAMHS

Child and family consultation service The Child and Family Centre 79 Axe Street Barking United Kingdom IG11 7LZ

Study participating centre Tower Hamlets CAMHS

Emmanuel Miller Centre 11 Gill Street Poplar London United Kingdom E14 8HQ

Study participating centre Central & North West London CAMHS

7a Woodfield Road London United Kingdom W9 2NW

Study participating centre Barnet, Enfield and Haringey CAMHS

Holly Oak, Edgware Community Hospital Burnt Oak Broadway Edgware London United Kingdom HA8 0AD

Study participating centre West London CAMHS

92 Bath Road Hounslow London United Kingdom TW3 3EL

Study participating centre Hackney Children's Social Care

Hackney Service Centre 1 Hillman Street London United Kingdom E8 1DY

Sponsor information

Organisation

University College London

Sponsor details

Joint Research Office UCL 1st Floor, Maple House – Suite B 149 Tottenham Court Road London England United Kingdom W1T 7DN

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Findings of both phases will be disseminated through a publication in a high impact peer reviewed journal, an internal report, and conference presentations. Results will also be published (in age-appropriate language) on the UCL, AFC and NHS Hospital/CAMHS websites.

Intention to publish date

01/12/2018

Individual participant data (IPD) sharing plan

The current 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?
Participant information sheet	version V1.6	28/10/2016	07/11/2016	No	Yes
Participant information sheet	version V1.6	28/10/2016	07/11/2016	No	Yes
Participant information sheet	version V1.6	28/10/2016	07/11/2016	No	Yes
Participant information sheet	version V1.6	28/10/2016	07/11/2016	No	Yes
Participant information sheet	version V1.6	28/10/2016	07/11/2016	No	Yes
Participant information sheet	version V1.6	28/10/2016	07/11/2016	No	Yes
<u>Protocol article</u>	protocol	30/10/2017		Yes	No
HRA research summary			26/07/2023	No	No