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Examination of a web-based Integrated Bipolar Parenting Intervention (IBPI) for bipolar parents of young children (aged 3-10)

Submission date
08/07/2013

Recruitment status
No longer recruiting

Registration date
12/08/2013

Overall study status
Completed

Last Edited
18/05/2017

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 find out whether it would be useful to adapt an existing parenting programme called Triple P Online to include specific information and ideas for parents with a mental disorder called bipolar disorder. This may improve the parenting experience for both parents and children and reduce the possibility of future problems for children of bipolar parents.

Who can participate?
People with a diagnosis of bipolar disorder who are aged 18 or over with at least one child aged between 3 and 10 years old and have internet access

What does the study involve?
A member of the research team arranges a time for an interview which takes place over the phone. Initially, they ask some questions to confirm eligibility for the study. The study requires that a bipolar disorder diagnosis is verified using an interview. This is conducted with all participants, unless this assessment has occurred during a previous study by the Spectrum Centre for Mental Health Research within the last 6 months. The interview takes about 1 hour and 15 minutes to complete over the telephone. Participants are randomly allocated to one of two groups. One group is provided with access to the Integrated Bipolar Parenting Intervention (IBPI) and should continue with any other treatments or care plans in place. The second group do not have access to the site during the period of the study. This group is vital to the success of the study to assess the effectiveness of the care offered to the first group. All participants in the second group are given access to the site after the end of the study if it is found to be helpful or cause no harm. IBPI consists of 16 modules. It is designed so that one module is completed each week over a period of 4 months. Each module may take an hour to complete online and then involve planning activities during the subsequent week. If participants have more than one child they are required to pick one to focus on during completion of the programme. All participants are asked to complete three telephone interviews during the 12 months of their study participation (upon joining, and then after 6 and 12 months). These telephone interviews take about 45 minutes to complete. Participants are also asked to complete a number of

questionnaires on five separate occasions (upon joining, and then after 4, 6, 9 and 12 months). Most of these are completed online, but one is via telephone. The online questionnaires take about an hour to fill in and the questionnaire completed over the phone takes about 5 minutes. Up to 10 parents can participate in an interview following the programme to express their views on IBPI, including elements that they found helpful as well as any challenges to using the web programme. Fifteen children of the parents involved in the study can take part in two interviews, once before and once after their parents' completion of the programme to find out about the children's emotions and their experience of family life. The interviews for parents last about an hour and the interviews for the children last about 45 minutes. The children's interviews involve using a programme called 'In My Shoes' (IMS), which is a computer-assisted interview for communicating with children. All interviews take place in participant's homes and are recorded as long as specific consent has been obtained.

What are the possible benefits and risks of participating?
By participating in the study there is an opportunity to get support that has been shown to be effective in previous studies combined with a package of support materials for bipolar disorder drawing on the trialists' expertise of developing and evaluating interventions. All participants are given the access to the programme, although for some participants this is at the end of the study rather than at the beginning. Some participants also have the opportunity to participate in interviews to give feedback on their experiences and thereby have a direct influence on the development of the programme. This study encourages participants to think about their past experiences and it is possible that thinking about these may result in some distress. The research team are sensitive to this and an online parent support group (peer support forum) is available to support discussion of this. In the event of concerns, the research team can be contacted directly and a list of support organisations will be supplied to all participants.

Where is the study run from?
Lancaster University (UK)

When is the study starting and how long is it expected to run for?
November 2012 to March 2015

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof. Steven Jones
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
MR/J011886/1

Study information

Scientific Title
An exploratory randomised controlled trial of a web-based Integrated Bipolar Parenting Intervention (IBPI) for bipolar parents of young children (aged 3-10)

Acronym
IBPI

Study objectives
To develop an Integrated Bipolar Parenting Intervention by combining informative material about Bipolar Disorder with an existing parenting intervention, Triple P Online, in consultation with a Service User Research Group consisting of individuals including parents with Bipolar Disorder and carers of people with Bipolar Disorder.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Greater Manchester East, 27/11/2012, ref: 12/NW/0749

Study design
Randomised Intervention; Design type: Web-based Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bipolar Disorder

Interventions
1. Intervention arm: Web-based integrated bipolar parenting intervention comprising the online Triple P parenting intervention alone. The intervention has been developed through collaboration between a multidisciplinary group of mental health professionals and service users with experience of bipolar disorder

Focus groups have taken place with individuals who took part in the first phase of the project (the qualitative analysis of recovery themes) to ensure that the intervention is appropriate and acceptable to individuals early in the course of bipolar disorder. Furthermore, a service user consultation group have also been provided.

2. Treatment as Usual Arm (TAU)

Follow Up Length: 12 months

The Intervention arm will receive the IPBI intervention for 4 months and then get follow-up at 4, 6, 9 and 12 months. The other arm of the trial is the Treatment as Usual Arm (TAU) they will be followed up at the same time points.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Feasibility (recruitment) measured at baseline
2. Feasibility (retention) measured at 12-months post randomization
3. Acceptability (website usage data) measured during intervention
4. Acceptability (qualitative interviews) measured 4-months post randomization

Key secondary outcome(s))
1. Strengths and Difficulties Questionnaire (SDQ) - Child Behaviour, measured at baseline, end of intervention (4 months), and 6-, 9-, and 12-months post randomization
2. Eyberg Child Behavior Inventory (ECBI) - Child Behaviour, measured at baseline, end of intervention (4 months), and 6-, 9-, and 12-months post randomization
3. Parenting Scale (PS3) - Parenting, measured at baseline, end of intervention (4 months), and 6-, 9-, and 12-months post randomization
4. Parenting Sense of Competancy Scale PSOC) Parenting, measured at baseline, end of intervention (4 months), and 6-, 9-, and 12-months post randomization
5. Parenting Stress Index (PSI) - Parenting, measured at baseline, end of intervention (4 months), and 6-, 9-, and 12-months post randomization

Tertiary outcome measures:
1. Internal States Scale (ISS) - Parent symptoms, measured at baseline, end of intervention (4 months), and 6-, 9-, and 12-months post randomization
2. Centre for Epidemiologic Studies Depression Scale (CES-D)- Parent symptoms, measured at baseline, end of intervention (4 months), and 6-, 9-, and 12-months post randomization
3. Altman Mania Rating Scale (AMRS) - Parent symptoms, measured at baseline, end of intervention (4 months), and 6-, 9-, and 12-months post randomization
4. Confusion, Hubbub and Order Scale (CHAOS) - Parent symptoms, measured at baseline, end of intervention (4 months), and 6-, 9-, and 12-months post randomization
7. Structured Clinical Interview for DSM-IV-TR AXIS 1 DISORDERS - LIFE (SCID-LIFE)- Parent Symptoms, measured at baseline, 6- and 12- moths post-randomisation
8. In My Shoes Computer Assisted Interview for Children - Child perspectives on family functioning, measured at baseline and 4 months post randomization

Completion date
03/03/2015

Eligibility

Key inclusion criteria
1. Individuals who have received a research-confirmed clinical diagnosis of bipolar disorder
2. Individuals who are parents of at least one child aged between 3 and 10
3. Individuals must have at least 10 hours of weekly contact with their child
4. Can provide written informed consent
5. Can communicate in English
6. Have access to the internet and a telephone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Individuals who are currently experiencing or have experienced within the last month, an acute episode of major depression or mania
2. Individuals referred into the study during an acute episode will wait until they have been out of episode for one month before entering the study. Nevertheless, it is expected that most participants will have subsyndromal mood symptoms

Date of first enrolment
27/11/2012

Date of final enrolment
01/01/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lancaster University
Lancaster

United Kingdom
LA1 4YW

Sponsor information

Organisation
Lancaster University (UK)

ROR
https://ror.org/04f2nsd36

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) Grant Code: MR/J011886/1

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

Results article		01/09/2017		Yes	No
Protocol article	protocol	06/06/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes