The E Sibling Project - an online information and peer support resource

Submission date 06/12/2012	Recruitment status No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 06/12/2012	Overall study status Completed	[_] Statistical analysis plan [X] Results
Last Edited 03/10/2018	Condition category Mental and Behavioural Disorders	[] Individual participant data

Plain English summary of protocol

Not provided at time of registration and not expected to be available in the future

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 13536

Study information

Scientific Title

Exploratory randomised controlled trial of an online multi-component psychoeducational intervention for siblings of individuals with first-episode psychosis

Study objectives

Siblings of individuals with first episode psychosis (FEP) are both a vulnerable group to develop mental ill health due to the negative impact caused by the psychosis within the family, as well as being the most effective and natural agents to promote service users recovery. This study aims to develop and evaluate an online multi-component psychoeducational intervention for this commonly overlooked group of resources and family members. The intervention aims to enhance siblings knowledge about psychosis and their coping capacity, thus reducing their vulnerability to mental ill health as well as improving their contribution to the service users recovery. The intervention content and delivery formats will be designed as informed by evidence in the literature as well as the siblings inputs through consultations and an expert advisory group. Mixed methods incorporated within the MRC phased research design for complex interventions will be used to develop and undertake a preliminary evaluation of the intervention. Qualitative data collection methods such as focus groups and semi-structured individual interviews with siblings will be employed in conjunction with a factorial design randomised trial with several outcome measures to test the effectiveness, feasibility and acceptability of the newly developed intervention with the target population.

Ethics approval required

Old ethics approval format

Ethics approval(s) First MREC, 22/11/2012 ref: 12/LO/1537

Study design Randomised interventional study

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Other

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 Mental Health; Psychosis

Interventions

E Sibling Project, It is anticipated that the final intervention will comprise multiple components and the following characteristics: psychoeducation focusing on information-giving on psychosis, common treatment and management strategies for symptoms with a feature called "Ask the Expert" and a peer support element that uses a virtual discussion network with secured and moderated discussion boards on commonly encountered issues and experiences to facilitate mutual sharing and discussion between siblings.

Follow Up Length: 3 months

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

Siblings' mental wellbeing using Warwich-Edinburgh Mental Wellbeing Scale measured at baseline, 10 weeks, at end of using intervention and after 20 weeks.

Secondary outcome measures

 Knowledge of mental health using Mental Health Knowledge Schedule (MAKS) measured at baseline, 10 weeks, at end of using intervention and after 20 weeks
 Positive and negative experience of caring using Experience of Caregiving Index (ECI) measured at baseline, 10 weeks, at end of using intervention and after 20 weeks
 Self efficacy using the Assessment of Perceived General Self-Efficacy (APGSE) measured at baseline, 10 weeks, at end of using intervention and after 20 weeks

Overall study start date

01/05/2013

Completion date

31/12/2014

Eligibility

Key inclusion criteria

1. Aged 16 years or above

2. Has a brother or sister receiving or has received service from a local EIPS over the last three years

- 3. Is based within Greater London or Berkshire areas themselves
- 4. Has at least weekly contact with their ill brother or sister on average over the last 3 months
- 5. Understands English in usual online communications
- 6. Has daily access to internet use
- 7. Male or female participants

Participant type(s)

Patient

Age group

Adult

Sex Both

Target number of participants UK Sample Size: 144;

Key exclusion criteria

1. Siblings of individuals whose primary diagnosis is not first-episode psychosis or who is not/ has not been under the care of Early Intervention in Psychosis Service within the last three years at the time of joining the trial

2. Siblings themselves who have a diagnosed major mental illness that require secondary /specialised mental health care treatment, either as medication or talking/ psychological therapy

Date of first enrolment 01/05/2013

Date of final enrolment 31/12/2014

Locations

Countries of recruitment England

United Kingdom

Study participating centre King's College London London United Kingdom SE1 8WA

Sponsor information

Organisation King's College London (UK)

Sponsor details Division of applied biomedical research London England United Kingdom WC2R 2LS Keith.brennan@kcl.ac.uk

Sponsor type University/education

Website http://www.kcl.ac.uk/

ROR https://ror.org/0220mzb33

Funder(s)

Funder type Government

Funder Name NIHR Doctoral Research Fellowship (UK) ref: DRF-2011-04-129

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	26/04/2013		Yes	No
<u>Results article</u>	results	01/10/2014		Yes	No
Results article	results	01/09/2016		Yes	No