ISRCTN40650639 https://doi.org/10.1186/ISRCTN40650639

An online psychosocial intervention for young people with appearance-altering conditions (YP Face IT)

Submission date
05/06/2014

Recruitment status
No longer recruiting

Registration date
05/06/2014

Overall study status
Completed

Last Edited
25/11/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
One in 44 young people (YP) have a visible difference ('disfigurement') as a result of injuries (e.g. burns), treatment (e.g. cancer treatment), skin conditions (e.g. psoriasis), or conditions from birth (e.g. birthmarks). Looking different can have a great effect in a society with a huge emphasis on appearance. About one third experience difficulties like bullying, social anxiety, body image dissatisfaction and low self-esteem, which impact on social presence, health behaviours and academic performance. If not addressed, social anxiety and body image dissatisfaction can lead to conditions including anxiety, depression and eating disorders in adulthood. Research shows YP need self-management skills as an alternative or addition to medical/surgical solutions, but evidence-based psychosocial interventions are rare and access to such services is limited. In collaboration with YP, we have developed an online intervention (YP Face It: www.ypfaceit.co.uk) based on our effective adult programme. Using illustrations, videos and interactive activities it provides advice and teaches coping skills based on cognitive behavioural therapy and social skills training. It aims to reduce social anxiety and appearance-related distress. In this study, we are evaluating the intervention before conducting a large-scale study.

Who can participate?
Sixty young people (aged 12-17) with an appearance-altering condition will be eligible to take part.

What does the study involve?
Participants will be randomly allocated to receive normal care or normal care plus the YP Face It online intervention. Young people will participate in the study for 1 year. If they are allocated to receive YP Face IT they will be asked to do seven sessions on a home computer or tablet. They will do one session a week. Each session takes 40-50 minutes and young people will also need to practice new skills during the week. At the start, middle and end of the year, you will fill in questionnaires about how you are and what kind of things you do. Three months into the study,

some young people (not all) will be asked to talk about what its been like being in the study so far. After a year, some young people (not all) will be asked about what it was like being in the study.

What are the possible benefits and risks of participating?
We hope this important study will help us to find out the best way to support young people who are worried about the way they look and to help them to live a full and happy life. Many young people enjoy taking part in research and feel that it is worthwhile helping researchers to find ways to support young people like them. The difficulties or risks in taking part are that young people need to give up time to do the questionnaires and interviews. If they are in the YP Face IT group they will need to do all the sessions as well. There is also a possibility that young people may find parts of it hard work as it talks about common worries such as being teased and asks them to think about appearance worries. However, if young people are unhappy with any part of the research or have any worries you can talk to the lead researcher or the Clinical Psychologist, who is an expert in providing support to young people with appearance concerns.

Where is the study run from?
GP practices in Bristol, Bath, South Gloucestershire, North Somerset, Wiltshire and Swindon will be helping recruit young people to the study.

When is the study starting and how long is it expected to run for?
The study starts in July 2014 and is expected to run until June 2016.

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

Who is the main contact?
Dr Heidi Williamson
heidi3.williamson@uwe.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Heidi Williamson

Contact details
University of the West of England
Frenchay Campus
Coldharbour Lane
Bristol
United Kingdom
BS16 1QY
-
heidi3.williamson@uwe.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16513

Study information

Scientific Title
A feasibility study to inform an RCT to evaluate an online psychosocial intervention for young people with appearance-altering conditions (YP Face IT)

Acronym
YP Face IT

Study objectives
Is it acceptable and feasible to conduct an RCT to evaluate YPF as an adjunct to treatment as usual (TAU) in a primary care setting?

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/SW/0058; First MREC approval date 14/05/2014

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Topic: Children, Primary Care; Subtopic: Not Assigned; Disease: All Diseases

Interventions

A total of 60 patients will be randomised to either intervention (YP Face IT) or treatment as usual (control)

YP Face IT: Using illustrations and interactive activities, YP Face IT provides advice and teaches coping skills based on cognitive behavioural therapy and social skills training. YP randomised into the intervention group will receive an e-mail/letter with a YPF website link, secure username and password to access the intervention using a home computer/tablet. The intervention takes 13 weeks to complete: seven weekly sessions (sessions take 40-50 minutes to complete) plus a booster session 6 weeks later.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Body Esteem Scale; Timepoint(s): Baseline, 13, 26 and 52 weeks

Secondary outcome measures
1. EQ-5D-5L; Timepoint(s): baseline, 13, 26, 52 weeks
2. Perceived Stigmatisation Questionnaire; Timepoint(s): baseline, 13, 26, 52 weeks
3. Self-Perception Profile; Timepoint(s): Baseline, 13, 26, 52 weeks
4. Social Anxiety Scale; Timepoint(s): Baseline, 13, 26, 52 weeks

Overall study start date
01/07/2014

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Young people aged 12-17 (and a parent/carer) with an appearance-altering condition/injury /treatment experiencing appearance-related distress/teasing/bullying
2. Access to a home computer/tablet and the internet
3. Fluency in English. Audio available for those who struggle/tire reading text (e.g. dyslexia)
4. Normal/corrected-to-normal vision

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit

17 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
32

Key exclusion criteria
1. Clinical depression, psychosis, eating disorder
2. Post-traumatic stress disorder (PTSD) or within 12 months of traumatic injury
3. Learning disability that compromises informed consent (GPs may not have a full record of learning disabilities. Researcher will ask YP and parent if academic support is required, and if so, discuss suitability)
4. Currently receiving psychological intervention in secondary care

Date of first enrolment
01/07/2014

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of the West of England
Bristol
United Kingdom
BS16 1QY

Sponsor information

Organisation
University of the West of England (UK)

Sponsor details

Frenchay Campus
Coldharbour Lane
Bristol
England
United Kingdom
BS16 1QY

Sponsor type
University/education

ROR
https://ror.org/02nwg5t34

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK); Grant Codes: PB-PG-1112-29014

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
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?
Results article	results	22/11/2019	25/11/2019	Yes	No
HRA research summary			28/06/2023	No	No