Title page

Type of paper: original research

Title: Young Persons' Face IT (YP Face IT), a web-based self-help psychosocial intervention for adolescents distressed by appearance-altering conditions and injuries: a feasibility study for a parallel randomized controlled trial.

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Abstract

Background: Visible differences resulting from wide-ranging congenital or acquired conditions, injuries or treatments can negatively impact adolescents' psychological well-being, education and health behaviours. Alongside medical interventions, appearance-specific cognitive behavioural and social skills training to manage stigma and appearance anxiety may improve psychosocial outcomes. YP Face IT (YPF), is a web-based seven session self-help program plus booster quiz, utilising cognitive behavioural and social skills training, for young people (YP) struggling with a visible difference. Co-designed by adolescents and psychologists, it includes interactive multi-media and automated reminders to complete sessions/homework. Adolescents access YPF via a health professional who determines its suitability and remotely monitors clients' usage.

Objective: To establish the feasibility of evaluating YPF for 12-17 year olds self-reporting appearance-related distress and/or bullying associated with a visible difference.

Methods: Randomized controlled trial with nested qualitative and economic study evaluating YPF compared with usual care (UC). Feasibility outcomes included: viability of recruiting via GP practices (face to face and via patient databases) and charity advertisements; intervention acceptability and adherence; feasibility of study and data collection methods and health professionals' ability to monitor users' online data for safeguarding issues. Primary psychosocial self-reported outcomes collected online at baseline, 13, 26 and 52 weeks were: appearance satisfaction (Appearance Subscale from Mendleson et al's (2001) Body Esteem Scale); social anxiety (La Greca's (1999) Social Anxiety Scale for Adolescents). Secondary outcomes were; self-esteem; romantic concerns;

perceived stigmatization; social skills and healthcare usage. Participants were randomised using remote web-based allocation.

Results: Thirteen charities advertised the study yielding 11 recruits, 13 primary care practices sent 687 invitations to patients on their databases with a known visible difference yielding 17 recruits (2.5% response rate), four recruits came from GP consultations. Recruitment was challenging, therefore four additional practices mass-mailed 3,306 generic invitations to all 12-17 year old patients yielding a further 15 participants (0.5% response rate). Forty-seven YP with a range of socioeconomic backgrounds and conditions were randomised (26% male, 91% white, mean age 14 years (SD 1.7)); 23 to YPF, 24 to UC). At 52 weeks, 16 (70%) in the intervention and 20 (83%) in UC groups completed assessments. There were no intervention-related adverse events; most found YPF acceptable with three withdrawing because they judged it was for higher-level concerns; 12 (52%) completed seven sessions. The study design was acceptable and feasible, with multiple recruitment strategies. Preliminary findings indicate no changes from baseline in outcome measures among the UC group and positive changes in appearance satisfaction and fear of negative evaluation among the YPF group when factoring in baseline scores and intervention adherence.

Conclusion**:** YPF is novel, safe and potentially helpful. Its full psychosocial benefits should be evaluated in a large-scale RCT, which would be feasible with wide-ranging recruitment strategies.

Trial registration: ISRCTN40650639

Keywords**:** physical appearance, body image, visible difference, disfigurement, adolescents, young people, psychological support, online intervention.

Introduction

Approximately one in 44 individuals have a condition or injury that noticeably affects the appearance of their face, skin or body shape [1]. Referred to as visible differences, these distinct changes result from congenital (e.g. cleft lip, birthmark), neurological (e.g. facial palsy), genetic (e.g. neurofibromatosis) or acquired conditions (e.g. acne). Advances in life-saving treatments are also increasing survivorship associated with an altered appearance resulting from traumatic injury (e.g. burn) and disease (e.g. meningitis). Appearing 'different' in a society that venerates looks can have profound effects during adolescence; a vulnerable period when social comparison with peers/celebrities is high, romantic interest is burgeoning, and appearance impacts self-esteem [2]. Research shows commonalities in the experiences of young people (YP) with a variety of appearance-altering conditions [3]; 30-50% struggle with social stigma (e.g. teasing, bullying, peer rejection, unwanted attention from strangers [4]) and/or experience appearance-related distress [5]. If not addressed, these experiences can lead to low self-esteem, social anxiety and avoidance [6,7], poor social and emotional development [8], reduced school performance [9], difficulties with romantic relationships [10], unemployment [11], depression [12], self-harm and suicidality [13]: a health, social and economic burden to society.

While surgical and medical advances to ameliorate appearance-altering conditions are advancing, they are not a cure-all [3] and, contrary to expectations, the severity, cause, and location of a visible difference do not reliably predict distress [14]. Adjustment is largely determined by intervening socio-cognitive factors, including perceived satisfaction with social support and acceptance, fear of negative evaluation by others and social confidence [15]. These factors are potentially amenable to change via psychosocial interventions that

offer an adjunct or alternative to medical/surgical solutions and provide skills to tackle stigmatisation and appearance-related distress.

Research [16] points to a dearth of evidence-based, cost-effective and appearance-specific interventions for YP. Within UK primary healthcare these YP rarely meet criteria for referral to Child and Adolescent Mental Health Services or waiting lists are long, and those receiving secondary healthcare for their condition often have no/limited access to psychological support [17]. Stakeholders (e.g. clinicians and parents) also report barriers preventing YP from seeking or accepting psychological, particularly face-to-face, support around such a sensitive issue. These include travelling to specialist appointments, fear of further stigmatisation and social anxiety/avoidance [18]. Acknowledging that numbers of YP experiencing poor mental health is increasing as psychological services are rationed, the UK's National Health Service (NHS) has called for innovative and cost-effective interventions that promote self-management and resilience [19]. An appearance-specific web-based psychosocial intervention could broaden access to support for those with appearance-related distress and improve quality through evidence-based standardized care.

In adults with a visible difference, a randomised control trial (RCT) of a multi-session web-based intervention (Face IT) has proved beneficial. Centred on Kent's Integrated Model of Psychosocial Distress and Intervention for Individuals with Visible Differences [20], Face IT integrated cognitive behavioural therapy (CBT) and social skills training (SST), reduced anxiety-related concerns and was comparable to face-to-face CBT [21]. Following the Medical Research Council framework for the development of complex interventions [22], we worked with YP to co-design an age-appropriate and guided self-help web-based intervention (Young Person's Face IT, or YP Face IT) based on Face IT [18]. YP Face IT (YPF) is

for 12-17 year olds with any appearance-affecting condition who are experiencing social stigma and/or appearance-related distress.

This article reports the results of a study which explored the feasibility of evaluating YPF compared to usual care (UC) using an RCT design and provided data to estimate the parameters required to design a definitive trial. There is no standardised treatment for this patient group, the type and frequency of UC was therefore recorded. The feasibility of recruiting participants via primary care and charitable organisations was also examined. General Practitioners (GPs) are accessible to most YP and parents, and charities for those with a wide range of appearance-altering conditions (e.g. www.changingfaces.org.uk) are approached by parents or YP for advice [18]. Both could provide immediate access to evidence-based appearance-related support; including while the YP is waiting for, or to preclude, referral to secondary care services.

Objectives

1. Numbers of eligible participants recruited via primary care practices and charities, including reasons for non-participation.
2. Participants' views on study design.
3. Acceptability of YPF intervention and adherence.
4. Acceptability of safeguarding processes.
5. Completion of outcome and resource use measures (for future economic evaluation).
6. Variation of UC provided.
7. Responses to patient-reported outcome measures, to inform the selection of a primary outcome measure and to test for harm and potential effectiveness of YPF (the trial was not powered to test statistically significant impact).

8. Sample size for a definitive trial.

Methods

Trial design

This parallel-group randomised controlled feasibility trial compared YP Face IT plus usual care (UC) with UC only (control), and included a nested economic and qualitative study and online pre- and post-assessments at 13, 26 and 52 weeks after randomization. Data analysts (PW, EM, TP) were blind to group allocation; participants were not. The trial was pre-registered and full protocol published [23]. The UK National Research Ethics Service Committee South West provided ethics approval (14/SW/0058).

Recruitment

Recruitment was via general practitioner (GP) practices and charitable organisations supporting those with a range of appearance-altering conditions (e.g. the UK's Cleft Lip and Palate association; www.clapa.com). Charities promoted the study via their websites or newsletters. Advertisements were designed alongside service users' involvement, outlined the study and included the research team's contact details.

GP practices were briefed on the study protocol in a 30-minute session. Practices utilised a medical diagnosis coding system to identify eligible patients with an appearance-affecting condition, and excluded those deemed unsuitable (e.g. condition resolved). Identified YPs were posted a personal invitation and information sheet. For those under 16 years old, letters were addressed to parents/carers who were asked to discuss participation with their child. A reminder, sent four weeks later to non-respondents, included a response form to indicate why they declined and a study-addressed envelope. Staff were also

encouraged to introduce the study to potential participants during consultations and provide a leaflet.

In a user-involvement meeting, GPs noted that database records were inaccurate and they had difficulties identifying eligible patients. Therefore, in a change to the published protocol, subsequent GP practices that joined the study used mass mail-out to all their 12-17 year olds patients using an online mail management solution (www.cfhdocmail.com); rather than GPs deciding who to invite, all 12-17 year olds could decide upon their eligibility. Letters were addressed to parents/carers of those under 16 years old, as above.

Interested YP/parents contacted the research team who answered questions and confirmed eligibility with the YP (including parent/carer if YP <16 years) via the telephone. Informed consent was obtained by participants completing and posting a consent form, or verbally consenting via a recorded telephone call.

Participants

When developing YPF, we sought advice from young people, parents and health professionals regarding the age range of the intervention's target audience and other eligibility criteria [18]. Eligible YP were 12 to 17 year old UK residents with any appearance-affecting condition who self-identified as experiencing appearance-related distress, teasing or bullying, were fluent in English (YPF has a reading age of 12 years and audio clips are available on YPF for those who struggle reading text), with internet literacy and access to an internet-enabled device. YP were ineligible if they had a registered learning disability, a diagnosis of clinical depression, psychosis, eating disorder, post-traumatic stress disorder (PTSD), or were within 12 months of a traumatic injury. PTSD is a risk for those disfigured through trauma [24]. Those under 16 years old required a parent/carer to join the study, those aged 16 and 17 were encouraged to inform and involve their parent/carer, but this

was not mandatory. Practice staff provided views on recruitment procedures and supervising their patients using YPF.

Intervention

YPF was developed by the Centre for Appearance Research, is owned by the University of the West of England and hosted by Dataphiles plc (www.dataphiles.co.uk). Details of creators and affiliations are provided on the homepage. The participatory action approach used to develop YPF is reported elsewhere [18]. Version three (www.ypfaceit.co.uk) was used in this trial; during which the content was frozen and program glitches addressed. The YP Face IT homepage (Figure 1) is freely accessible to all (only the sessions require a personal login) and provides easy-to-understand videos describing the intervention for young people and comprehensive details of the therapeutic content for health professionals.

YPF aims to help YP overcome social anxiety, manage social stigma and reduce negative thoughts about their appearance that can lead to unhelpful behaviours. It has seven weekly sessions (each taking approximately 30-40 minutes to complete) including homework (e.g. to practice strategies for managing teasing) and a booster session (quiz) completed six weeks later. Sessions are summarized in Table 1 with more detail in the YPF development and protocol papers [18, 23]. YPF has a restricted administration area where user accounts are set-up by a supervising health professional, and usage is recorded (e.g. date and duration of access, pages viewed, text/numeric responses to embedded reflective and homework activities/quizzes). YP can utilise a journal that stores personal data and quiz/survey responses, and a closed forum to share and receive advice from fellow participants, moderated Monday to Friday by researchers. Participants were allocated a participant identification number and data were protected via a secure portal using 128 bit

SSL encryption. Users are provided with an e-mail address to report glitches. To check for safeguarding issues (e.g. disclosure of abuse, suicidality, intervention-related adverse events), researchers with safeguarding training (e.g. www.nsahealth.org.uk) reviewed users' activity weekly. The feasibility of nominated staff at six GP practices performing this task for their patients was assessed; they received 10 minute training and a prompt sheet detailing how to access the administration area, and were advised to follow their safeguarding protocols and note actions on the website. Researchers also recorded and referred concerns to the team's clinical psychologist who decided what, if any, additional support was required.

Figure 1: YP Face IT homepage

Control

All participants received usual care (UC), with those in the intervention arm receiving YPF in addition to UC. Since there is no standardised treatment for this patient group,

details of the type and frequency of UC received was collected via health economic data collection tools, primary care note reviews, and patient interviews.

Table 1: Content of YP Face IT.

Session title	Session description
1: Common Problems	Common difficulties and feelings experienced by young people with visible differences, shared experiences form similar others and review of helpful and unhelpful coping strategies.
2: Improve your social skills	Using positive body language and talking skills to promote self-confidence and manage negative reactions form others.
3: Don't be SCARED, REACH OUT	Recognising the impact of one's behaviour on others and using the 'REACHOUT' toolbox to manage social stigma and challenging situations (Reassurance, Effort and Enthusiasm, Assertiveness, Courage, Humour, Over there, Understanding and Try again). Interactive videos allow users to practice new techniques.
4: 'Think, Feel, Do'	Introducing the link between thoughts, feelings and actions; the common misconceptions young people with visible differences have about the thoughts and actions of others; tips on how to challenge negative thoughts using 'catch it; check it; change it'. Users practice this process using interactive social scenarios.
5: SMART goals	Realistic and achievable goal-setting to overcome social anxiety and to combat self-imposed limitations. Goal setting examples and testimonials from positive role models. Option to explore issues around romantic relationships.
6: Beating Anxiety	Symptoms of anxiety; anxiety management techniques; using 'testing the water' and the 'fear ladder' techniques to overcome social anxiety and achieve goals, creating their own fear ladder and setting goals.
7: Looking at your progress	Revision session on whole programme.
8: Booster Quiz	Interactive quiz on key learning points. Facility to identify and revisit areas that the user is struggling with or wishes to revise.

Procedure

Following baseline assessments, participants were randomised to the intervention or control group in block sizes of four, to ensure similar numbers in each group, using an automated Web-based service provided by Bristol Randomised Trials Collaboration (independent clinical trials unit). The intervention group received an email with instructions on how to log-on using a unique username and password. Additional guidelines for YP and parents on how to make the most of YPF and support their child, and a log to record health resource usage were e-mailed and posted. Participants were advised to complete all seven weekly sessions consecutively, but could choose to complete a session over two days. They

were prompted to select a time for their next session via an embedded diary and sent automated reminders (and to a parent/carer if preferred) via text and/or email 24 and 2 hours before their session was due. Automated text/e-mails reminded participants to complete homework if not completed five days after a session, and invited participants to complete the 'booster' quiz six weeks after session seven. At the end of sessions, participants could complete an embedded two-minute survey about their views of the session.

Control participants received an email or telephone call informing them of the allocation and emphasizing the importance of continued participation. During the trial four newsletters were sent to all YP and parents to encourage engagement.

At 13, 26 and 52 weeks, YP and parents were e-mailed a link to an online questionnaire hosted by www.qualtrics.com designed to take 30 minutes to complete. Non-completers were prompted via e-mail to complete questionnaires up to three times. After 13 (5 parents, 11 YP) or 52 weeks (3 parents, 5 YP, 8 practice staff) participants were invited to share their experiences via a 30 minute semi-structured telephone interview.

Outcomes

To inform future recruitment into a trial and YPF's acceptability and safety, the study focused on: comparison of recruitment rates via targeted letters, mass mail-out, charities and consultations; reasons YP with an appearance-altering condition declined participation; questionnaire completion rates and missing data; YPF acceptability (indicated by logged user statistics, session feedback and percentage of YP/practice staff reporting login issues); YP and parent/carer views on YPF/UC, and the number and nature of safeguarding concerns and any action required. To determine the acceptability of the trial protocol, participants were asked about recruitment processes, random allocation, communicating with

researchers and safeguarding procedures. Proposed psychosocial outcome measures for the future definitive RCT were assessed at baseline, 13, 26 and 52 weeks via online self-report questionnaires. Candidates for a primary outcome measure in the definitive trial were:

1. 10 item Appearance Subscale from the Body Esteem Scale (BESA) utilising a Likert scale (0 = never to 4 = always). Higher scores indicate greater appearance satisfaction. Scale reliability and validity has been previously demonstrated in adolescents [25]. In the present study, the BESA also showed strong internal consistency (α = 0.88).
2. 22 item Social Anxiety Scale for Adolescents (SAS) utilising a Likert scale (1 = not at all to 5 = all the time). We used total SAS score and subscales scores for Fear of Negative Evaluation by others (FNE), Social Avoidance and Distress in new situations (SAD-N) and in general situations, for example with peers (SAD-G). Higher scores indicate greater anxiety. Scale reliability and validity has been previously demonstrated in adolescents [26]. In the present study, the total SAS (α = 0.93), the FNE (α = 0.91), the SAD-N (α = 0.86) also showed strong internal consistency. However the internal consistency of SAD-G was comparatively less acceptable (α = 0.60).

Secondary outcome measures explored for their acceptability and sensitivity to change were:

1. Five item Romantic Appeal (RA) and five item Global Self-Esteem (SE) subscales from the Self-Perception Profile. YP choose which of two statements are “really true for me”= 1 or “sort of true for me”= 2, and decide whether the selected statement is “really true for me”= 3 or “sort of true for me”= 4. Higher scores indicate greater satisfaction with romantic appeal or higher self-esteem. Scale reliability and validity

has been previously demonstrated in adolescents [27]. In the present study, the RA showed reasonable internal consistency (α = 0.68) and the SE good internal consistency (α = 0.77).

3. Twenty-one item Perceived Stigmatisation Questionnaire (PSQ) utilising a Likert scale with reversed scored items (never = 5 or 1 to always = 5 or 1). We calculated total PSQ score and subscales scores for Absence of Friendly Behaviour (AFB), Confused and Staring Behaviour (CSB) and Hostile Behaviour by others (HB). Higher scores indicate greater perceived stigmatisation. Scale reliability and validity has been previously demonstrated in adolescents [28]. In the present study, the total PSQ (α = 0.92), the CSB (α = 0.90) and the HB (α = 0.93) also showed strong internal consistency. However the internal consistency of AFB was comparatively less acceptable (α = 0.68).

2. Communication, Cooperation, Assertion, Responsibility, Empathy, Engagement and Self-control subscales (46 items) from the Social Skills Improvement System with a Likert scale (0 = never to 3 = almost always). Higher scores indicate greater perceived competence. Scale reliability and validity has been previously demonstrated in adolescents [29]. In the present study internal consistency scores for these subscales were good and ranged from α = 0.70 to α =0.84. Full details of all Chronbach's Alpha scores can be found in Table 3.

3. Health-related quality of life was measured by the EQ-5D-5L questionnaire, a standardised instrument to measure generic health status for clinical and economic appraisal. The EQ-5D-5L has been validated in a diverse patient population in multiple countries [30]. Responses to this questionnaire are given utility values to

produce a utility score for the health state Quality-adjusted life years (QALY) can be estimated by weighting time spent in that health state by its utility score.

YP were asked if they had engaged in deliberate self-injury (DSI) over the past 3 months, (no; once or twice; three times or more). YPF was not designed to target DSI, but our previous evidence, suggesting DSI may be associated with appearance-related anxiety, demanded an assessment of its prevalence to determine if YPF should address this issue in the future. To establish the feasibility of collecting parent data as proxy indicators of their child's wellbeing and the impact of the intervention, parents/carers completed parent versions of the SAS and SSIS at the same assessment points. YP were given a £10 Amazon voucher on completion of measures at 13, 26, 52 weeks.

Identifying and measuring resource use

Resource use data was collected at 13, 26 and 52 weeks. Parents/carers completed an online study-specific resource use questionnaire (RUQ) to collect data regarding all-cause and appearance-related health care and other resource use. The RUQ included questions on community based contacts, including contacts with the GP, mental health nurse psychologists, 111 service (UK telephone service for accessing non-emergency healthcare), school nurse, orthodontist, and mental health services; secondary care contacts with emergency, outpatient and inpatient visits; contacts with social worker; charities; and personal costs accessing private services, make-up and wig specialists and equipment. YP were also asked about days off school, which would potentially expand the future economic evaluation to take a societal perspective on costs. Those aged 16 and 17 years completed the RUQ if a parent/carer was not recruited. For comparison, study-specific case report forms were mailed to participants' GP practices, to report on healthcare resource use.

Sample size considerations

No formal power calculations are undertaken in feasibility studies, instead a suitable number of participants are recruited to gain knowledge about factors such as attrition and recruitment in relation to feasibility outcomes [31]. We aimed to recruit 60 YP to allow acceptability and completion rates to be estimated with error margins of +/-13%, and with 1:1 randomisation, n = 30 allocated to YPF would have in excess of 80% power for detecting a 50% or lower completion rate against an anticipated rate of 75%.

Analysis

Acceptability of intervention and study design

Descriptive statistics report YP sample characteristics; website use; and rates of recruitment, retention and data completion. To inform acceptability of the chosen outcome measures, percentage missing values were determined at each assessment point and qualitative feedback was collated from parents and YP via interviews. Interviews were digitally recorded and transcribed verbatim. Practice staff, parent and YP data were analysed separately using inductive thematic analysis [32]. Coding and theme development were driven by data content rather than existing concepts and involved: reading and becoming familiar with the full dataset; preliminary data coding to identify initial themes which were clustered with a descriptive summary provided for each, and discussion of findings to reach consensus. Practice staff findings are published elsewhere [33], only data relevant to the study objectives are reported here.

Health economic data analysis

We applied the Devlin et al [34] UK preference weights for the 5L version to derive utility scores for young people, with the caveat these preference weights were developed for adults. We derived a one year QALY using the area under the curve method [35], and

report QALY gain from baseline per trial arm. We derived rates of RUQ completion at 13, 26 and 52 weeks, compared resource use reported by participants and by GP practices, and costed resources using of UK health and social care estimates of unit costs [36, 37]. Analyses were performed in STATA v14.

Primary outcome and intervention impact

The trial was not powered to test statistically significant impact however, to inform the selection of a primary outcome measure and test for harm and potential effectiveness of YPF, the impact on repeated outcome measures was analysed descriptively with some inferential methods used to describe the sample and estimate parameters. Statistical comparisons of outcomes were made between the two arms at 13, 26 and 52 week follow-up. Independent samples t-test assessed if they differed at any given stage. Prior reasoning would suggest no or minimal systematic change in the control group and a high degree of correlation between baseline and follow up data. If there is a systematic effect in the intervention group there is the possibility that those at the worrying end of a scale may show greater change compared to those with relatively less worrying scores. Consequently, the rate of change in outcomes with baseline may differ between the two arms**.** Using ANCOVA the groups were therefore compared on the primary outcome candidate measures allowing for initial commensurate baseline value (i.e. Main Effect was "Randomised Group", "Baseline" was the Covariate and the Interaction Effect was Group by Covariate). For the intervention group, multiple regression considered outcome with respect to engagement (number of YPF sessions completed) after factoring in baseline position. At each stage all available data were analysed, *P* values and partial eta-squared, a measure of effect size, are used to describe the data rather than confirm effects. Analyses were run using SPSS V23.

Results

Recruitment rate and participants

Thirteen charities advertised the study once, resulting in 11 participants. Thirteen practices in South West UK (practice sizes ranged from 3,618 to 15,750 patients, M = 11,523, SD = 3,597), with a range of index of multiple deprivation (IMD) scores (1 - 10, where 1 = 10% most deprived), posted personalised invitations to 687 YP with an appearance-affecting condition. Identifying potential participants took two to three hours per practice. Seventeen YP consented to participate, giving a recruitment rate of 2.5%. Over 3 months four additional GP practices (practice size = 8,314 - 10,726 patients, M = 9,450, SD = 8830) mass-mailed 3,306 letters to all 12-17 year old patients, this took approximately 45 minutes per practice and 15 YP consented to participate, giving a recruitment rate of 0.5% (Figure 2). Including this extension, recruitment was March to October 2015 and the last participant completed follow up September 2016.

YP and parents reported that letters from GPs provided credibility, with some expressing a preference for generic letters because YP were not singled out based on their difference and could decide if they had appearance-related distress. Practice staff preferred mass mail-out over targeted letters because it was time efficient and they found it difficult to judge patient suitability for targeted letters. In-consultation recruitment was low (n=4). Some staff found raising the option of appearance-related psychosocial support during consultations was difficult, especially when they perceived YP were expecting medical treatment only.

Forty-seven YP (26% male, 91% White, mean age = 14.2 years (SD=1.7)) from a range of socioeconomic backgrounds (IMD sample scores ranged from 1 to 10 with a mean of 6.78 (SD=2.71)) and with various conditions were randomised to YPF (n=23) or UC (n=24). Forty

parents/carers were recruited. Demographic information and descriptive statistics for YP at all time-points are in Tables 2 and 3. At baseline 25/47 YP (53%) reported being bullied. In comparison to population norms [25, 26], 25/47 YP (53%) reported lower than average body esteem (M=2.3, SD=0.8), 25/47 YP (53%) reported higher than average social anxiety (M=44.5, SD=13.5), and 8/47 (17%, majority female) disclosed DSI.

Table 2. Key characteristics of young people at baseline

		Control (n=24)	**YPF (n=23)**
Age, mean (SD)		14 (1.95)	14 (1.42)
Female, n (%)		15 (62.5)	20 (87)
Ethnicity, n (%)	White British	20 (83.3)	23 (100)
	White other	-	-
	Chinese	1(4.2)	-
	Black African	-	-
	Black Caribbean	-	-
	Black British	-	-
	Indian	-	-
	Asian British	-	-
	Dual heritage	2 (8.3)	-
	Other	1 (4.2)	-
Condition, n (%)	Skin (e.g. psoriasis, eczema)	11 (45.8)	11 (47.8)
	Craniofacial (e.g.: cleft and facial palsy)	5 (20.8)	5 (21.7)
	Scarring (e.g. burns and surgery)	3 (12.5)	4 (17.4)
	Birthmark (e.g. port wine stain)	1 (4.2)	-
	Body form (e.g. visible pacemaker, leg longer, missing finger, fused toes)	4	3 (13)
DSI, n (%)	Once or twice	1 (4.2)	4 (17.4)
	Thrice or more	1 (4.2)	2 (8.7)
	Total incidence (% female)	2 (100)	6 (60)

SD: standard deviation DSI: Deliberate Self-Injury in past 3 months

Reasons for participation and non-participation

Parents and YP cited lack of alternative support as a reason for participating: "*I was hoping something like this would come our way one day*" (parent, child with craniofacial condition); "*you can't get help about these concerns*" (female, 17 years, scars); "*the students that bullied me got offered counselling and I didn't get anything*!" (female, 16 years, craniofacial condition). Of the 687 YP approached via targeted letters, 81 (11%) provided reasons for declining. Of these, 69 (85%) had no appearance concerns, four (5%) had

concerns they did not wish to discuss, six (7%) had no available time, one (1%) did not want their friends to know and one (1%) had no internet-enabled device.

Figure 2: CONSORT flow diagram

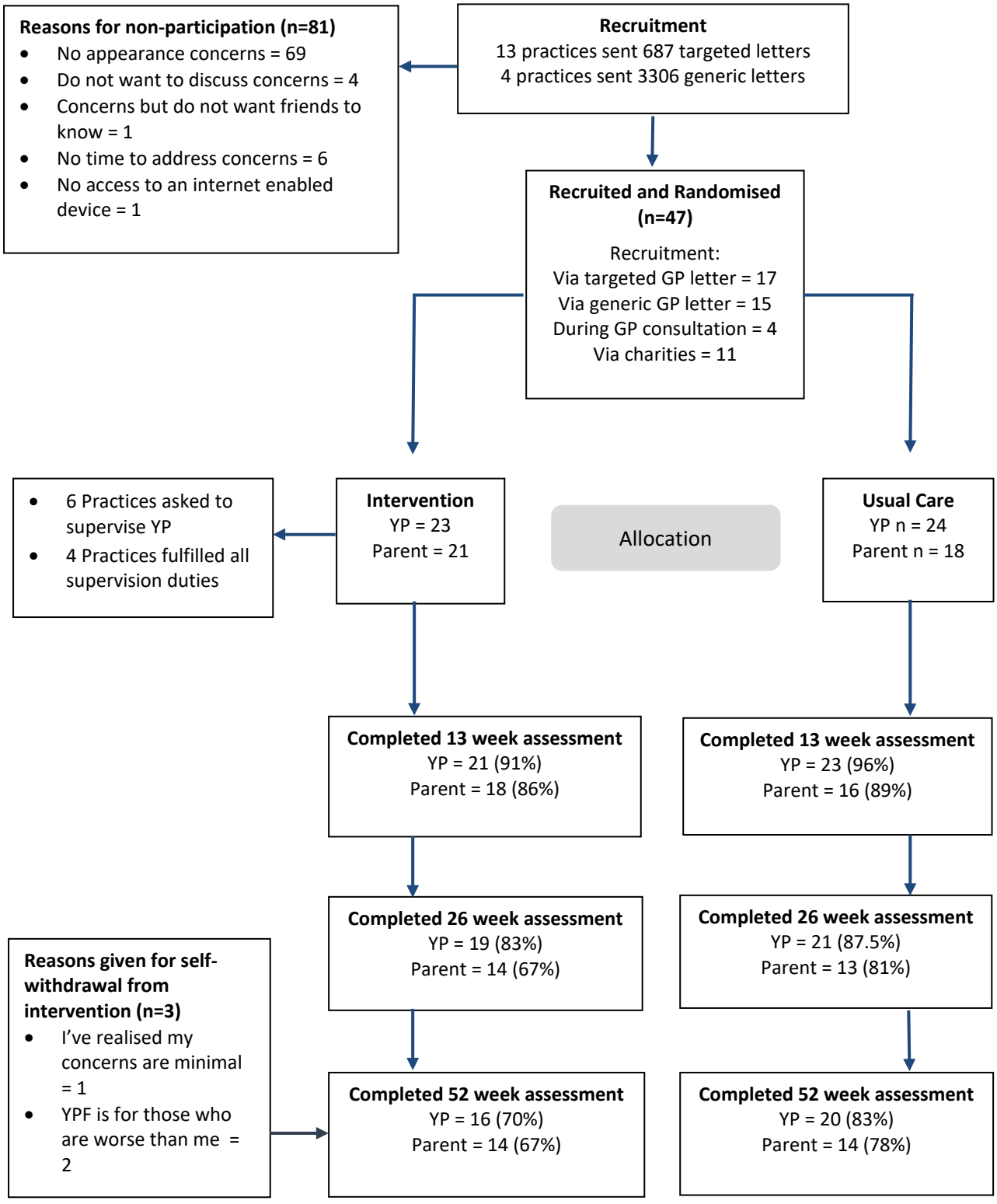

Table 3. Descriptive statistics on young people's outcome measures at all time-points

Variable	α	Group	Baseline Control (n=24) YPF (n=23)	13 weeks Control (n=23) YPF (n=21)	26 weeks Control (n=21) YPF (n=19)	52 weeks Control (n=20) YPF (n=16)
BES-A	.88	Control	2.45 (0.83)	2.40 (0.96)	2.24 (1.09)	2.69 (0.90)
mean (SD)		YPF	2.07 (0.72)	2.09 (0.54)	2.19 (0.81)	2.31 (0.55)
SAS Total	.93	Control	42.47 (14.01)	40.39 (14.46)	41.86 (15.34)	38.70 (14.61)
mean (SD)		YPF	45.71 (13.03)	42.33 (10.51)	38.58 (12.11)	37.94 (11.74)
FNE	.91	Control	19.65 (7.64)	18.48 (8.34)	19.24 (8.32)	17.10 (7.70)
mean (SD)		YPF	21.81 (7.06)	20.0 (5.78)	18.11 (7.12)	17.25 (5.59)
SAD-N	.86	Control	15.78 (5.33)	15.0 (5.25)	14.86 (5.97)	14.13 (4.70)
mean (SD)		YPF	16.19(5.60)	15.71 (5.01)	14.05 (3.69)	14.12 (4.70)
SAD-G	.60	Control	7.04 (2.50)	6.91 (2.59)	7.76 (2.98)	7.45 (2.96)
mean (SD)		YPF	7.86 (2.03)	7.10 (2.28)	6.42 (2.32)	6.56 (2.37)
RA	.68	Control	2.54 (0.66)	2.47 (0.73)	2.51 (0.81)	2.95 (0.81)
mean (SD)		YPF	2.21 (0.66)	2.31 (0.57)	2.45 (0.48)	2.56 (0.60)
SE	.77	Control	2.98 (0.66)	3.07 (0.78)	2.90 (0.94)	3.17 (0.74)
mean (SD)		YPF	2.63 (0.83)	2.70 (0.76)	2.75 (0.84)	3.08 (0.79)
PSQ	.92	Control	2.12 (0.57)	2.01 (0.54)	2.06 (0.59)	1.92 (0.54)
mean (SD)		YPF	2.25 (0.61)	2.13 (0.52)	1.94 (0.59)	1.96 (0.52)
AFB	.68	Control	2.30 (0.42)	2.12 (0.56)	2.39 (0.46)	2.33 (0.47)
mean (SD)		YPF	2.35 (0.36)	2.06 (0.37)	2.21 (0.43)	2.25 (0.47)
CSB	.90	Control	2.04 (0.76)	1.78 (0.65)	1.78 (0.63)	1.60 (0.61)
mean (SD)		YPF	2.06 (0.84)	1.98 (0.83)	1.72 (0.78)	1.80 (0.78)
HB	.93	Control	1.90 (0.99)	1.77 (0.90)	1.97 (0.94)	1.77 (0.99)
mean (SD)		YPF	2.29 (0.95)	2.10 (0.73)	1.85 (0.88)	1.78 (0.67)
Communication	.78	Control	14.75 (2.45)	15.39 (2.41)	14.67 (2.31)	15.15 (2.62)
mean (SD)		YPF	13.78 (3.10)	13.71 (2.41)	14.05 (2.82)	14.81 (2.83)
Cooperation	.79	Control	15.12 (3.27)	15.95 (3.45)	15.09 (3.56)	15.7 (4.50)
mean (SD)		YPF	13.95 (3.45)	13.66 (3.16)	14.21 (3.03)	15.25 (2.79)
Assertion	.73	Control	12.25 (3.52)	13.69 (3.64)	12.71 (3.69)	13.15 (4.73)
mean (SD)		YPF	12.08 (4.18)	13.04 (3.93)	13.37 (4.04)	14.00 (4.06)
Responsibility	.70	Control	15.58 (2.50)	15.95 (3.15)	16.38 (2.67)	16.3 (3.29)
mean (SD)		YPF	14.86 (3.42)	15.38 (3.13)	15.05 (4.03)	15.87 (3.66)
Empathy	.84	Control	14.79 (2.78)	13.85 (2.85)	14.19 (2.50)	15.25 (2.75)
mean (SD)		YPF	14.00 (3.31)	14.30 (2.81)	14.31 (3.23)	14.75 (2.59)
Engagement	.75	Control	14.16 (2.89)	15.21 (3.66)	14.67 (3.95)	15.55 (4.61)
mean (SD)		YPF	13.13 (4.24)	13.90 (4.10)	14.53 (4.06)	14.56 (4.56)
Self-control	.84	Control	10.62 (3.28)	11.86 (10.85)	11.43 (2.04)	12.15 (3.88)
mean (SD)		YPF	10.56 (4.19)	18.85 (3.33)	12.53 (2.95)	13.18 (3.98)

SD: standard deviation, α: Cronbach's α, BES-A: Body Esteem Appearance subscale, SAS total: Social Anxiety Scale total score, FNE: Fear of Negative Evaluation subscale, SAD-N: Social Avoidance and Distress New situations subscale, SAD-G: Social Avoidance and Distress among peers subscale, RA: Romantic Appeal subscale, SE: Self-esteem subscale, PSQ: Perceived Stigmatisation total score, AFB: Absence of Friendly Behaviour subscale, CSB: Confused and Staring behaviour subscale, HB: Hostile Behaviour by Others subscale.

Acceptability of study design

Interviewees typically endorsed an RCT design, "*I got UC, I didn't really mind, as long as I was using my time to help*" (female, 16 years, craniofacial condition), but parents who

cited lack of alternative support as a reason for participation reported their children were disappointed when allocated UC: "*she really wanted to be the one that tried YP Face IT, so that was very disappointing*" (parent, child with skin condition). Study newsletters and the facility to complete measures online were credited for maintaining study engagement: '*the newsletters were really nice … It keeps people engaged on my side of the study*' (Female, 17 years, Eczema, UC group), "*questions were easy, I did them on my phone which was useful,*" (male, 12 years, skin condition).

Retention of participants

In the intervention group three patients self-withdrew. One decided viewing YPF "*helped me realise there are bigger problems and I could be a lot worse off, I'm happy the way I am*" (female, 16 years, skin condition), two felt it was more suitable for those with greater concerns: "*it's more for people that are very insecure and need help*" (female, 15 years, birthmark).

Acceptability of intervention and safeguarding processes

Table 4 details YPF usage and session feedback. The number of those attempting each session decreased as participants progressed through the intervention. Notably, 12/23 (52%) attempted seven sessions, 9/23 (39%) completed the booster quiz. The time spent on each session by those who attempted it varied, from 1 (signed in to and left session) to 100 minutes, with a mean time ranging from 26.17 minutes (for session 7 which provides revision) to 47.60 minutes (session 2 which has the most content). Some completed a single session in two sittings. Percentage of session content viewed (an indication of adherence), by those attempting sessions, also varied and ranged from 10% to 100%. Sessions with the lowest completion rates were 1 (mean 87.13%) and 2 (mean 88.85%), but most of those

who persisted with the programme viewed all of the 7 sessions' material (indicated by a median of 100%).

Table 4. YP Face IT intervention (YPF) content and usage by participants (n = 23) in the Intervention Group and online session feedback.

Session	Number of YP in intervention group attempting session (% of sample)	Average minutes spent per session per person Mean (SD) Median (min-max)	Percentage of session content viewed per person. Mean (SD) Median (min-max)	Median (min-max) response to whether session was [1]interesting; [2]easy to understand; [3]helped me. Where 1=strongly agree, 2=agree, 3=don't know, 4=disagree, 5=strongly disagree.
1	23 (100)	33.04 (26.80) 27 (1-100)	87.13 (24) 100 (28-100)	[1]2 (1-2) [2]2 (2-2) [3]2 (1-2)
2	20 (87)	47.60 (26.10) 46 (6-90)	88.85 (24.82) 100 (10-100)	[1]2 (1-3) [2]2 (1-2) [3]2 (1-2)
3	17 (74)	29.18 (21.76) 25 (2-76)	94.53 (14.78) 100 (42-100)	[1]2 (1-3) [2]2 (1-2) [3]2 (1-3)
4	14 (61)	38.64 (23.69) 34.50 (14-83)	100 (0) 100 (100-100)	[1]2 (1-3) [2]2 (1-3) [3]2 (1-3)
5	13 (57)	42.92 (25.25) 33 (13-91)	96.15 (7.68) 100 (80-100)	[1]1 (1-1) [2]2 (2-2) [3]2 (1-2)
6	12 (52)	40.25 (23.95) 34 (6-89)	95.42 (8.91) 100 (75-100)	[1]1 (1-2) [2]2 (2-2) [3]2 (1-3)
7	12 (52)	26.17 (18.64) 22.50 (5-67)	100 (0) 100 (100-100)	[1]2 (1-2) [2]2 (1-2) [3]2 (1-2)
Quiz	9 (39)	31.33 (13.63) 30 (12-63)	100 (0) 100 (100-100)	

SD: standard deviation.

The only login errors and glitches reported (n=8) were with the booster quiz, these were addressed but accounted for five participants not completing the quiz. Of those attempting sessions, the majority agreed sessions were interesting, easy to understand and helpful. This was expanded upon during interview , "*it was really good, I found it very interesting listening to different ways of dealing with situations and the emotional side and sometimes you feel*

like you are the only one, but with YPF you know it's not just you" (female, 14 years, scarring).

Greatest variation in opinion was found in response to sessions 3 and 4 (managing challenging social interactions and challenging negative thoughts) where some indicated benefit from CBT more than SST and vice versa: "*I had social skills… but YPF made me think, notice things which were positive, made me aware of things, like the subconscious, it's a reminder that you're not the centre of the world. People will look and go 'ooh', but then carry on. It made me not wait till it's* [skin condition] *better and get on with life now*" (male, 15 years); "*The bit on anxiety was really helpful*" (male, 12 years, craniofacial condition). Some YP reported benefits from both*: "The SCARED acronym was helpful and Testing the Water was good for starting small changes, like talking to people*" (female, 14 years, craniofacial condition).

YP reported that YPF validated their concerns and increased their confidence in seeking psychological support via primary care, "*it's made me aware that you can get help, I'd be more open to see a GP, and more comfortable talking about it now*" (Male, 13 years, skin condition). There were also suggestions that YPF affected decisions around appearance-altering surgery: "*he's been asking us to look into an aesthetic operation. We had the appointment after he had started YP,F but he's changed his mind and decided he doesn't want it now, so YPF has been very useful*" (parent, child with scars).

Practice staff found supervision responsibilities brief (2-5 minutes per participant, per session) and straightforward, but only 59% of supervision tasks were completed; forgetting and lack of time were barriers to completion. YP did not disclose safeguarding issues via YPF data collection tools, nor did they use the discussion forum. There was no evidence (from following up those who withdrew and analyses of outcome measures) of any

intervention-related adverse events, but incidences of DSI at baseline were reviewed by the team's clinical psychologist who adhered to NHS guidelines for its management. This resulted in six YP with DSI being advised to seek GP support, and in 2 cases their GP was also informed via a letter.

Completion of outcome and resource use measures for future economic evaluation

The percentage of participants providing data via online questionnaires at each assessment point were high for YP in both arms ranging from 96-70% with (76%) overall completion at 52 weeks, but there was a 13% comparative reduction in completion at 52 weeks among the intervention group (see Figure 1). Data completion was 100% for psychosocial measures. For the EQ-5D-5L, 16/23 (70%) in the YPF and 18/24 (75%) in the UC group provided enough data to derive quality adjusted life years. Completion of the online RUQ was over 50% at 52 weeks for all categories, except community mental health services and days off school (Table 5). The control group provided more complete data than in the YPF group. Table 6 reports resource use for all medical reasons.

Table 5. Completeness of the EQ-5D-5L and resource use data

	YPF (n=23)						**UC (n=24)**					
	Week 13		**Week 26**		**Week 52**		**Week 13**		**Week 26**		**Week 52**	
	N	%	N	%	N	%	N	%	N	%	N	%
EQ-5D-5L	21	91	19	83	16	70	23	96	21	88	20	83
QALY complete cases					16	70					18	75
GP services	13	57	13	57	15	65	19	79	14	58	18	75
Mental health services	7	30	2	9	9	39	8	33	7	29	13	54
Social services	13	57	13	57	15	65	19	79	14	58	18	75
Other NHS community services	13	57	13	57	15	65	19	79	14	58	18	75
Outpatient appointments	17	74	16	70	12	52	21	88	16	67	13	54
Accident & Emergency	19	83	16	70	14	61	21	88	17	71	16	67
Inpatient nights	19	83	16	70	16	70	21	88	17	71	17	71
Hospital tests	19	83	16	70	16	70	21	88	16	67	18	75
Private services/expenses	19	83	15	65	15	65	19	79	16	67	17	71
Days off school	7	30	9	39	8	35	10	42	10	42	6	25

Resource complete cases	5	22	2	9	5	22	5	21	5	21	9	38

Table 6. Number of participants who completed the resource use questions at each time points, the number who used the resource, the mean units of resource used and their mean costs.

	YPF						Usual care					
	N[1]	**N[2] >0**	**Mean Resource Use**	**SD**	**Mean Cost (£)**	**SD (£)**	**N[1]**	**N[2] >0**	**Mean Resource Use**	**SD**	**Mean Cost (£)**	**SD (£)**
GP visits	6	3	3.0	3.3	132	147	13	9	2.0	2.3	88	103
GP calls	6	1	0.2	0.4	5	11	13	2	0.7	2.2	19	60
GP home visits	6	0					13	0				
GP nurse visits	6	2	1.3	2.2	19	31	13	4	0.7	1.2	10	17
GP nurse calls	6	0					13	0				
GP nurse home visits	6	0					13	0				
Mental health nurse	6	0					13	1	0.2	0.6	7	24
Psychologist	6	0					13	3	0.6	1.3	86	184
111 calls	6	0					13	0				
School nurse	6	2	0.5	0.8	6	11	13	2	0.2	0.6	3	8
Orthodontist	6	3	1.7	1.9	167	186	13	5	0.6	1.1	62	112
Mental health services	0	0					6	1	0.7	1.2	75	185
Outpatient appointments	11	5			199	312	14	5			210	486
Accident & Emerg. visits	13	3	0.3	0.6	41	83	16	4	0.3	0.6	41	79
Inpatient nights	13	0	0.0	0.0	0	0	16	1	0.1	0.3	22	89
Social worker contacts	6	0					13	0				
Charity contacts	6	0					13	1	0.2	0.6	0	0
Private counselling	13	2	1.8	6.4	58	191	15	1	0.2	0.8	n/a	n/a
Private services	13	2	0.3	0.9	5	19	15	0				
Make-up and wig specialist	13	0					16	0				
Make-up, wigs, and other equipment	12	1			1	3	13	1	0.1	0.3	4	13

1 Number of people who completed the resource use question at 13, 26, and 52 weeks allowing for a one year cost to be derived. 2 Of those who completed, number of participants who reported having used the resource.

The number of completed resource use categories over one year is small. Participants who completed questionnaires did not use some community- based services, such as GP nurse telephone calls and visits. Potential cost drivers of the intervention include GP visits,

community mental health services and secondary care visits. When asked about appearance-related resource use only, differences between arms were smaller and fewer participants reported use. Resource use completion rates were higher using GP practices medical records review proformas. Practice staff completed these resources for 27 to 30 of the 47 patients in the trial, whereas only 19 patients self-reported these contacts.

Variation of usual care

Participants were asked to record any psychosocial support they received for appearance concerns. One reported receiving support from a private counsellor and one from an NHS counsellor, both were in the UC arm.

Selecting primary outcome measure and estimate of impact on outcome measures.

Independent samples t-tests at 13, 26 and 52 weeks did not show statistically significant differences between the two arms on any measure. Positive changes to the primary outcome candidate measures in the intervention arm (BES-A and the FNE subscale of the social anxiety scale) were found when factoring in baseline scores and engagement with the programme (see Tables 7 and 8).

After adjusting for BES-A baseline scores, there were statistically significant main effects for randomised group at 13 (P=.001), 26 (P=.001) and 52 weeks (P=.02) and interaction effects at 13 (P<.001), 26 (P=.002) and 52 weeks (P=.006). Engagement with the intervention was a significant predictor of BES-A scores at 13 (P=.02) and 26 weeks (P<.001) but this was not maintained at 52 weeks (P=.29). After adjusting for FNE baseline scores, there were statistically significant main effects for randomised group at 13 (P=.047) and 26 (P=.02) weeks and interaction effects at 13 (P=.03) and 26 (P=.007) weeks, but no statistically significant main (P=.29) or interaction (P=.22) effects at 52 weeks. Engagement

with the intervention was a significant predictor of FNE scores at 13 (*P*=.01) and 26 weeks (*P*=.01) but again this was not maintained at 52 weeks (*P*=.25).

Table 7. Change in appearance and social anxiety outcomes at each time-point and between each arm when factoring in baseline values

Assessment point	Measure	Valid *n*	Main effect for randomised group		Measure at Baseline		Interaction	
			P- value	η_p^2	*P-value*	η_p^2	*P-value*	η_p^2
13 weeks	BES-A	44	.001	.253	<.001	.585	<.001	.287
	SAD-N	44	.08	.071	<.001	.534	.09	.068
	FNE	44	.04	.095	<.001	.593	.03	.108
	SAD-G	44	.91	.000	<.001	.453	.91	.000
26 weeks	BES-A	40	.001	.257	<.001	.388	.002	.242
	SAD-N	40	.005	.203	<.001	.422	.001	.255
	FNE	40	.02	.135	<.001	.290	.007	.187
	SAD-G	40	.23	.039	.002	.229	.05	.099
52 weeks	BES-A	36	.02	.153	<.001	.445	.006	.212
	SAD-N	36	.14	.065	<.001	.526	.08	.088
	FNE	36	.29	.034	.002	.273	.22	.046
	SAD-G	36	.57	.010	<.001	.356	.27	.037

BES-A: Body Esteem Appearance subscale, SAD-N: Social Avoidance and Distress New situations, FNE: Fear of Negative Evaluation, SAD-G: Social Avoidance and Distress among peers. Thresholds for partial eta-squared (η_p^2): < .0025 indicates a trivial inconsequential effect; .0025 to .01 indicates a small effect; .01 to .06 indicates a moderate effect; .06 to .14 indicates a medium sized effect; .14 to .30 indicates a large effect; .30 to .50 a very large effect and > .50 indicates a huge effect.

Table 8: The impact of engagement with the YP Face IT intervention on appearance and social anxiety outcomes at each time-point when factoring in baseline value

				Baseline measure		Engagement	
Assessment point	Measure	Valid *n*	R^2	$\hat{\beta}_1$	*P value*	$\hat{\beta}_2$	*P value*
13 weeks	BES-A	21	.396	.427	.03	.461	.02
	SAD-N	21	.340	.627	.007	-.158	.45
	FNE	21	.574	.637	.001	-.420	.01
	SAD-G	21	.439	.677	.001	-.173	.35
26 weeks	BES-A	19	.682	.057	.69	.816	<.001
	SAD-N	19	.371	.430	.05	-.581	.01
	FNE	19	.337	.070	.73	-.571	.01
	SAD-G	19	.349	.217	.29	-.557	.01
52 weeks	BES-A	16	.202	.282	.27	.323	.21
	SAD-N	16	.438	.684	.008	-.331	.15
	FNE	16	.216	.344	.18	-.295	.25
	SAD-G	16	.285	.561	.04	-.292	.26

BES-A: Body Esteem Appearance subscale, SAD-N: Social Avoidance and Distress New situations, FNE: Fear of Negative Evaluation, SAD-G: Social Avoidance and Distress among peers

Although the study was not powered to confirm effects, results suggest that YPF may improve BES-A and FNE for those at the worrying end of these scales, and that increased engagement with YPF may be a contributory factor.

The BES-A would be an appropriate primary outcome measure for a future RCT. The BES-A is frequently used in adolescent body image research because it is reliable, has normative data and has good face validity among adolescents [e.g. 38], it provides a general measure of satisfaction with appearance and is not condition specific, making it appropriate for those with any appearance-altering condition. In this study, YP fed back that it was quick and easy to complete and results indicated it is sensitive to change among those completing the intervention.

Recruitment for full RCT

A future RCT design would be amenable to analysis using ANCOVA with a baseline by group interaction and n = 53, 70, 86 per arm would have 80, 90, 95 % power for detecting anticipated effects; this power is supported by lower bounds on effect sizes from this feasibility study. This study indicates 76% full data completion at 52 weeks, recruiting N=186 will give complete data on N=140 (90% power).

Discussion

Principle findings

This study explored the feasibility of using a RCT to evaluate the effectiveness and cost-effectiveness of YP Face IT (YPF), an online psychosocial intervention to support YP with appearance-related anxiety. Results indicate YPF is a welcome, safe and acceptable intervention with the potential to fill a gap in care provision, and suggest an RCT design

would be acceptable and feasible with wide-ranging recruitment strategies, using the Body Esteem Appearance subscale as primary outcome measure.

Lessons learned will inform a future RCT, particularly around engaging young people in appearance-related research, an extremely sensitive topic rarely discussed with adults in primary care settings [18]. Recruiting from this group is notoriously challenging [39] and pertinent barriers and facilitators to recruitment identified in this study are discussed in detail elsewhere [33]. In summary, educating staff on the importance of normalising conversations about appearance and validating rather than minimising concerns in primary care settings, could increase YP help-seeking behaviour and reduce perceived stigma around receiving psychosocial support. Despite these challenges, recruitment via charitable organisations and GP practices is feasible, but to achieve the recommended large trial sample size, in addition to advertising via a wide range of relevant charities, using social media and a mass mail-out approach from large GP practices is recommended. This would also allow YP to decide whether or not their condition causes psychological distress, rather than GPs judging their suitability; which in this study often involved GPs second-guessing the objective severity of the visible difference. This recommendation aligns with evidence that an individual's subjective assessment of the impact of a visible difference is a better predictor of adjustment [14] and recommendations that health professionals should ask about, rather than assume, levels of distress [40].

The majority of YP found YPF sessions interesting and helpful, and retention and data completion strategies (e.g. online questionnaires, text reminders) were largely successful. Retention (76% of all YP completed data at 52 weeks) and intervention–adherence rates (52% completed the programme) were comparable to that demonstrated in similar studies using internet-based CBT for adolescent anxiety [41]. Nonetheless, and

particularly considering indications that increased engagement may improve outcomes, adherence could be improved. Feedback that YPF may not suit all (e.g. some felt it was suited to those with greater concern) suggests that more stringent inclusion criteria based on level of distress could be employed in future. However, given evidence that YPF does not cause harm, the preliminary nature of these findings and our aim to provide easily accessible support for all who want it, at this stage we recommend retaining current inclusion criteria and incorporating a subset analysis for those who score highly at baseline.

Although the potential benefits and nature of blended care (a combination of eHealth and guidance from a care provider) are being debated [42], definitive trials could also consider preventing attrition by including, for example, a telephone call from the supervising health professional to YP who do not progress as expected or support from a peer who has completed the programme. Qualitative data suggests that depending on individual needs, some YP may benefit from additional motivation and support. However the YPF forum, an opportunity to gain peer support and included on request from our YP advisory group, was not utilised. The value of this feature should be confirmed in a larger trial.

The safeguarding protocol for ensuring vulnerable YP were followed up by the research team was successful. Whether it is feasible or necessary for practice staff to review YP data weekly is undecided; insufficient time/forgetting resulted in some staff failing to review accounts. However, as it appears that YP do not disclose safeguarding issues via the website (all cases of DSI were reported in response to a single item within outcome measures) it may be more feasible for researchers to continue with weekly checks (to confirm this finding) whilst determining whether automated reminders to staff to review patient data increases adherence. This data could ultimately provide GPs with information

to determine the need for a follow-up appointment after the YP has completed YPF. Finally, to replace a task fulfilled by the team's clinical psychologist in this study, in future trials YP will be signposted to appropriate sources of support for DSI within YPF.

We found that resource use data collection via online questionnaires is potentially burdensome and completion rates are low. Patients reported use of resources beyond the health and social care payer perspective, with high costs of private counselling and other expenses. A future economic evaluation could include a private perspective on costs and should rely on resources being completed through GP practice proformas, complemented by participant self-report on use of private and other mental health services. Findings from the qualitative study also highlight that the follow-up of the future RCT will need to be long-enough to capture potential long-term health care savings accruing from YPF, such as cosmetic surgeries and other expensive treatments avoided.

Strengths

YPF is an innovative, easily accessible intervention with the potential to improve outcomes for YP with a visible difference and appearance-related distress who currently have limited access to evidence-based specialist support. Extensive reflection and user involvement, built in to the study design, identified a feasible recruitment strategy that ultimately provided sufficient data to address study objectives and inform the design of future trials. Independent randomization and use of well-established outcome measures ensured data was reliable and valid, and a primary outcome measure (Body Esteem Appearance Subscale) was selected.

Limitations

Because there is no best alternative therapy available for young people with a visible difference, apart from limited access to a mental health practitioner, there was no active

control arm. Whilst our initial concerns that YP randomised to receive UC may be disappointed were borne out, there was minimal evidence that this deterred participation. However, considering this disappointment and confirmation that there is little alternative support available, future trials should consider a wait-list control arm. A higher drop out in the YPF arm may have resulted from the increased burden associated with completing the intervention. Participants required an internet-enabled device, which may have restricted access to those with lower socioeconomic status; even though only one person identified this as a reason for declining involvement, this issue requires consideration. The majority ethnicity of the sample was white, which reflects a typical bias across appearance research [43] that needs addressing in future studies. Lastly, we relied on self-report measures that may result in reporting bias and YP were not blinded to their allocation.

Conclusion

We successfully delivered a novel online intervention for YP disclosing appearance-related distress associated with an appearance-altering condition and confirmed the feasibility of evaluating it against a UC control group using an RCT design, with high levels of data completeness and reasonable intervention adherence. Despite reporting a range of negative appearance-related experiences including bullying, self-harm, poor body esteem and social anxiety, participants had not sought appearance-related support or known how to do so. YPF may prove to be a feasible, cheap and acceptable source of immediate specialist support, particularly for those with low body esteem and high levels of social anxiety. Young people involved in the development of YP Face IT co-produced a video summarising this study, available on YouTube: https://www.youtube.com/watch?v=nwwVPpSCR3U.

Acknowledgements

This report is independent research conducted with the support of a research grant from the National Institute of Health Research grant number: PB-PG-1112-29014. The views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health.

Conflicts of interest

YP Face IT is owned by the University of the West of England and not the authors who created and/or are evaluating it.

Multimedia Appendix 1: CONSORT-EHEALTH checklist (V1.6.1)

References

1. Julian D, Partridge J. 2007. Face Equality campaign: The incidence and prevalence of disfigurement. https://www.changingfaces.org.uk/wp-content/uploads/2016/03/FE-Campaign-Epidemiology-2-pages.pdf. Archived at: http://www.webcitation.org/6zpPdhxIG.
2. Levine MP, Smolak L. Body image development in adolescence. In: Cash TF, Pruzinsky T, editors. Body image: A handbook of theory, research, and clinical practice. New York: Guilford Press; 2002. p.74-82. ISBN:1593850158
3. Rumsey N, Harcourt D. Visible difference amongst children and adolescents: issues and interventions. DEV NEUROREHABIL 2007;10(2):113-23. PMID: 17687984.
4. Lovegrove E, Rumsey N. Ignoring it doesn't make it stop: adolescents, appearance, and bullying. Cleft Palate Craniofac J 2005;42(1):33-44. https://doi.org/10.1597%2F03-097.5.1

5. Rumsey, N. Body image and congenital conditions with visible differences. In: Cash TF, Pruzinsky, T, editors. Body Image: A Handbook of Theory, Research, and Clinical Practice. New York: Guilford Press; 2002. p. 226–233. ISBN:1593850158
6. Masnari O, Schiestl C, Rossler J, Gutlein SK, Neuhaus K, Weibel L, Meuli M, Landolt MA. Stigmatization predicts psychological adjustment and quality of life in children and adolescents with a facial difference. J Pediatr Psychol 2013;38(2):162-172. PMID: 23172874.
7. Newell RJ. Altered body image: a fear-avoidance model of psycho-social difficulties following disfigurement. J Adv Nurs 1999;30(5):1230-1238. PMID: 10564423
8. Bull R, Rumsey N. The Social Psychology of Facial Appearance. London: Springer-Verlag; 1998. ISBN 978-1-4612-3782-2.
9. All Party Parliamentary Group on Body Image. 2012. Reflections on body image. URL:https://issuu.com/bodyimage/docs/reflections_on_body_image2. Archived at: http://www.webcitation.org/6zpRudNNt.
10. Griffiths C, Williamson H, Rumsey N. The romantic experiences of adolescents with a visible difference: exploring concerns, protective factors and support needs. J Health Psychol 2012;17(7):1053-1064. PMID: 22253328
11. Stone A, Wright T. When your face doesn't fit: employment discrimination against people with facial disfigurements. J Appl Soc Psychol 2013;43(3) https://doi:org/10.1111/j.1559-18162013.01032.x
12. Moss TP, Lawson V, White P. The Appearance Research Collaboration. Salience and Valence of Appearance in a Population with a Visible Difference of Appearance: Direct and Moderated Relationships with Self-Consciousness, Anxiety and Depression. PLoS ONE 2014;9(2):e88435. PMID:24516660

13. Gupta G. Depression and suicidal ideation in dermatology patients with acne, alopecia areata, atopic dermatitis and psoriasis. Br J Dermatol 2002;139(5):846-850 https://doi:org/10.1046/j.1365-2133.1998.02511.x

14. Moss TP. The relationships between objective and subjective ratings of disfigurement severity, and psychological adjustment. Body Image 2005;2(2):151-159. PMID: 18089183

15. Clarke AR, Thompson AR, Jenkinson E, Rumsey N, Newell R. CBT for Appearance Anxiety: Psychosocial Interventions for Anxiety due to Visible Difference. Oxford: Wiley; 2014. ISBN: 9781118523421.

16. Jenkinson E, Williamson H, Byron-Daniel J, Moss TP. Systematic Review: Psychosocial interventions for children and young people with visible differences resulting from appearance altering conditions, injury, or treatment effects. J Pediatr Psychol 2015 Nov-Dec;40(10):1017-1033. https://doi:10.1093/jpepsy/jsv048.

17. Williamson H, Rumsey, N. Perspectives of health professionals on the psychosocial impact of an altered appearance among adolescents treated for cancer and how to improve appearance-related care. J Psychosoc Oncol 2017;35(1):47-60. https://doi.org/10.1080/07347332.2016.1247407.

18. Williamson H, Griffiths C, Harcourt D. Developing young person's Face IT: Online psychosocial support for adolescents struggling with conditions or injuries affecting their appearance. Health Psychol Open 2015;2(2). https://doi.org/10.1177/22055102915619092

19. NHS England. 2015. Future in mind: Promoting, protecting and improving our children and young people's mental health and well-being. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/414024/Childrens_Mental_Health.pdf. Archived at: http://www.webcitation.org/6zvVsod8i

20. Kent G. Understanding the experiences of people with disfigurements: an integration of four models of social and psychological functioning. Psychol Health Med 2000;5(2):117-129. doi: 10.1080/713690187
21. Bessell A, Brough V, Clarke A, Harcourt D, Moss T, Rumsey N. Evaluation of the effectiveness of Face IT, a computer-based psychosocial intervention for disfigurement-related distress. Psychol Health Med 2012;17(5):565-577. https://doi.org/10.1080/13548506.2011.647701
22. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008;337:a1655. PMID: 18824488
23. Williamson H, Hamlet C, White P, Marques EM, Cadogan J, Perera R, Rumsey N, Hayward L, Harcourt D. Study protocol of the YP Face IT feasibility study: comparing an online psychosocial intervention versus treatment as usual for adolescents distressed by appearance-altering conditions/injuries. BMJ open. 2016;6(10):e012423. PMID: 27697878
24. Ehde DM, Patterson DR, Wiechman SA, Wilson LG. Post-traumatic stress symptoms and distress 1 year after burn injury. J Burn Care Rehabil 2000;21(2):105–111. PMID: 10752742.
25. Mendelson BK, Mendelson MJ, White DR. Body-esteem scale for adolescents and adults. J Pers Assess 2001;76(1):90-106. PMID: 11206302.
26. La Greca AM. 1999. Manual for the Social Anxiety Scales for Children and Adolescents. http://local.psy.miami.edu/people/faculty/alagreca/. Archived at http://www.webcitation.org/78EpcdXpW)

27. Harter S. 1998. The Self-Perception Profile for Adolescents Manual. https://portfolio.du.edu/SusanHarter/page/44210. Archived at http://www.webcitation.org/78Eq6UN6g.

28. Lawrence J, Fauerbach J, Heinberg L, Doctor, M, Thombs D. The reliability and validity of the perceived stigmatization questionnaire (PSQ) and the social comfort questionnaire (SCQ) among an adult burn survivor sample. *Psychol Assess;*2006;*18*(1):106–111 PMID: 21171795

29. Gresham FM, Elliott, SN. Social Skills Improvement System Rating Scales Manual. Minneapolis, MN: Pearson; 2008. ISBN: 139780749157067

30. EQ-5D Products. 2016. EQ5D-5L. http://www.euroqol.org. Archived at: http://www.webcitation.org/78Es6Xue6.

31. Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. BMC Med Res Methodol; 2010 Jul 16;10 (1):67.PMID: 20637084

32. Braun V, Clarke, V. Using thematic analysis in psychology. Qual Res Psycho 2006;3(2):77-101. https://doi.org/10.1191/1478088706.

33. Hamlet C, Williamson H, Harcourt D. Recruiting young people with a visible difference to the YP Face IT feasibility trial: a qualitative exploration of primary care staff experiences. Prim Health Care Res Dev 2017 Aug 14:1-8. https://doi: 10.1017/S1463423617000536.

34. Devlin N, Shah K, Feng Y, Mulhern B, van Hout B. Valuing health-related quality of life: An EQ-5D-5L value set for England. Health Econ. 2017; DOI: 10.1002/hec.3564 httpS://onlinelibrary.wiley.com/doi/10.1002/hec.3564/full.

35. Manca A, Hawkins N, Sculpher MJ. Estimating mean QALYs in trial-based cost-effectiveness analysis: the importance of controlling for baseline utility. Health Econ. 2005;14(5):487-96. https://doi.org/10.1002/hec.944

36. Curtis L, Burns A. Unit Costs of Health and Social Care. 2015. Personal Social Services Research Unit, University of Kent, Canterbury 2015. https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2015/. Archived at http://www.webcitation.org/78EqLDYa0.

37. Department of Health. 2015. NHS Reference Costs 2014 to 2015. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/577083/Reference_Costs_2015-16.pdf. Archived at http://www.webcitation.org/78EqivGSY.

38. Diedrichs P, Atkinson M, Garbett K, Williamson H, Halliwell, E, Rumsey, N. Evaluating an internet-based intervention designed to improve body image and psychosocial well-being among adolescent girls and their mothers: A cluster randomised controlled trial with mother-daughter dyads. Health Psychology 2016; 35(9): 996-1006. https://psycnet.apa.org/doi/10.1037/hea0000361

39. Gee C, Williamson H, Maskell J, Kimble R, Newcombe P. The challenges of recruiting adolescents for appearance-related research in a specialist tertiary hospital. J Paediatr Child Health 2018;54(11):1034-4810. https:// doi.org/10.1111/jpc.13942

40. Williamson H, Wallace M. When treatment affects appearance. In: Rumsey N, Harcourt D, editors. The Oxford Handbook of Appearance Psychology. Milton Keynes: Oxford University Press; 2012. p. 414-438. ISBN: 978-0-19-958052-1

41. Rooksby M, Elouafkaoui P, Humphris G, Clarkson J, Freeman R. Internet-assisted delivery of cognitive behavioural therapy (CBT) for childhood anxiety: Systematic review and

meta-analysis. J Anxiety Disord 2015;29:83-92. https://doi.org/10.1016/j.janxdis.2014.11.006

42. Wentzel J, Vander Vaart R, Bohlmeijer ET, van Gemert-Pijnen JEWC. Mixing online and face-to-face Therapy: How to benefit from blended care in mental health. JMIR Ment Health 2016;3(1):e9 PMID: 26860537.

43. Naqvi H. Saul K. Culture and ethnicity. In: Rumsey N, Harcourt D, editors. The Oxford Handbook of Appearance Psychology. Milton Keynes: Oxford University Press; 2012. p. 203-216. ISBN: 978-0-19-958052-1

Abbreviations

YP: Young People

CBT: Cognitive Behavioural Therapy

SST: Social skills training

YPF: YP Face IT

BID: Body image dissatisfaction

IMD: Index of multiple deprivation

BES-A: Body Esteem Appearance subscale

SAS: Social Anxiety Scale

FNE: Fear of negative evaluation subscale

SAD-N: Social anxiety in new situations subscale

SAD-G: Social anxiety in general situations subscale

PSQ: perceived stigmatization questionnaire

SSIS: Social Skills Improvement System

DSI: Deliberate self-injury

RUQ: resource use questionnaire