Study Title: A pilot study evaluating the effectiveness of information and therapy guides for improving the psychosocial wellbeing of people with facial palsy.

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There are no potential conflicts of interest

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, HRA, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

TABLE OF CONTENTS

To update table of contents (TOC), hover cursor over the table and ‘right click’. Choose ‘update field’, then ‘update entire table’.

1. SYNOPSIS

Study Title	A pilot study evaluating the effectiveness of information and therapy guides for improving the psychosocial wellbeing of people with facial palsy.	
Study Design	Feasibility/pilot study	
Study Participants	Adults with a diagnosis of facial palsy and/or their friends and relatives	
Planned Sample Size	140 participants	
Planned Study Period	July 2019 – May 2021	
	Objectives	**Outcome Measures**
Primary	To evaluate the effectiveness of Information and Therapy guides (ITG) at improving the psychosocial wellbeing of people with a diagnosis of facial palsy	Hospital Anxiety and Depression Scale Face-Q – Social function Face-Q – Psychological function Face-Q – Appearance-related psychosocial distress Facial Disability Index
Secondary	To evaluate the effectiveness of Information and Therapy guides at improving the psychosocial welling of family and friends of people with a diagnosis of facial palsy	Hospital Anxiety and Depression Scale Adult Carer Quality of Life Questionnaire
Tertiary	To evaluate the acceptability and usability of Information and Therapy guides for people with facial palsy and/or their family and friends	Patient satisfaction questionnaire

2. ABBREVIATIONS

ANCOVA	Analysis of Covariance
CBT	Cognitive Behavioural Therapy
CI	Chief Investigator
CRF	Case Report Form
CTRG	Clinical Trials & Research Governance, University of Oxford
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form

ITG	Information & Therapy Guide
NHS	National Health Service
NRES	National Research Ethics Service
OXTREC	Oxford Tropical Research Ethics Committee
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SOP	Standard Operating Procedure

3. BACKGROUND AND RATIONALE

Facial palsy is characterised by facial muscle weakness, typically due to facial nerve damage, and affects between 23 to 35 people per 100 000 (1). By far the most common cause of facial palsy is Bell's palsy, which affects approximately 20.2 people per 100 000 and is likely to have a herpetic trigger. Although up to 70% of people with Bell's palsy will make a full recovery, facial palsy is a condition with a heterogeneous presentation, with some people experiencing temporary unilateral weakness, with others having permanent, bilateral facial paralysis (2).

Some of the physical sequelae of facial palsy include difficulties with: eating, drinking, speaking, eyelid closure, pain, taste, muscle atrophy and synkinesis (3). Current management options include: injections of Botulinum Toxin A; facial therapy; facial reanimation surgery and surgery to the eyelid and/or tear duct (4). However, it is also important to note that it is not known how many patients with facial palsy have made a spontaneous recovery without treatment, as they are unlikely to present to facial palsy services.

Although there is no direct relationship between the degree of appearance change and reported distress (5), people with facial palsy typically experience higher levels of distress, compared to other forms of visible facial difference (6). This is believed to be due to the impact that facial palsy has on the face's ability to express emotions, which is a crucial aspect of face-to-face communication (7). This lack of facial expression of emotion can be interpreted by others as an indicator of boredom, hostility or disinterest, resulting in a higher number of negative social interactions (6). Indeed, impairment in smiling has been shown to be a significant predictor of anxiety and depression in individuals with facial palsy (8).

In a sample of 103 patients with facial palsy in the United Kingdom, 32.7% had significant levels of anxiety and 31.3% had significant levels of depression (5). This is compared to an estimated 8.33% for the general UK population (9). Furthermore, low self-esteem has been shown to be one of the strongest predictors of distress among people with facial palsy (10), indicating that difficulties with anxiety, depression and self-esteem are all significant factors which can affect the wellbeing of individuals with facial palsy.

Facial palsy can not only have an impact on the individual with facial palsy, but also on the physical and psychological wellbeing of friends, family members and carers. Indeed, the impact of caregiving on physical and psychosocial outcomes is well documented (11) and highlights the importance of focusing on not only the wellbeing of patients with facial palsy, but also their family members or carers.

The difficulties that patients across the United Kingdom experience accessing facial palsy services is well documented, with a freedom of information request in 2012 revealing that only 13% of Clinical Commissioning Groups routinely fund all types of facial palsy treatments, without requiring specialist funding approval (12). This means that patients often travel a long distance in order to access specialist multidisciplinary services, such as the Oxford Facial Palsy Service and may go some time without accessing support during the early stages of their condition.

Despite the significant impact of facial palsy on the psychosocial wellbeing of people with facial palsy, there is no research investigating the effectiveness of psychological interventions for people with this condition. As a result, a recent consensus document following a Delphi survey of patients, carers, clinicians and researchers highlighted research into identifying the types of psychological intervention that are most effective for people with facial palsy as being one of the key research priorities (13).

Although not researched yet in a facial palsy population, one type of psychological intervention that has been found to be effective at improving the psychosocial wellbeing of people with visible differences has been psychological self-help, including online or booklet-based self-guided cognitive behavioural therapy (CBT; see 14 for a review). With this in mind, the Oxford Facial Palsy Service secured funding from the charity “VTCT Foundation” to develop seven self-guided information and therapy guides (ITGs), for people with facial palsy and/or their friends or relatives, using evidence-based interventions such as cognitive behavioural therapy, social skills training and acceptance and commitment therapy.

This current study aims to pilot the use of these guides in order to assess their effectiveness at improving the psychosocial wellbeing of people with facial palsy and their friends and family. Eligible participants will complete a set of baseline measures prior to trialling the use of a relevant ITG over a period of four-to-six weeks. After the four-to-six weeks, participants will re-complete the measures completed at baseline, along with a questionnaire assessing the usability and acceptability of the ITGs.

4. OBJECTIVES AND OUTCOME MEASURES

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
Primary Objective To evaluate the effectiveness of Information and Therapy guides at improving the psychosocial wellbeing of people with a diagnosis of facial palsy	Hospital Anxiety and Depression Scale Face-Q – Social function Face-Q – Psychological function Face-Q – Appearance-related psychosocial distress	1) Prior to participant using ITG 2) After participant has used ITG for 4-6

	Facial Disability Index	weeks
Secondary Objectives To evaluate the effectiveness of Information and Therapy guides at improving the psychosocial welling of friends and relatives of people with a diagnosis of facial palsy	Hospital Anxiety and Depression Scale Adult Carer Quality of Life Questionnaire	1) Prior to participant using ITG 2) After participant has used ITG for 4-6 weeks
Tertiary Objectives To evaluate the acceptability and usability of Information and Therapy guides for people with facial palsy and/or their friends and relatives	Participant satisfaction questionnaire	1) After participant has used ITG for 2-3 weeks 2) After participant has used ITG for 4-6 weeks

5. STUDY DESIGN

Given that this study represents an initial pilot of the use of ITGs for people with facial palsy (and/or their friends and relatives), all eligible participants will receive the intervention (i.e. there will be no control group). As a result, this study will have a repeated-measures design.

Eligible participants will be recruited by one of two means:

1) Face-to-face of recruitment of OUH NHS patients during clinics at the Oxford Facial Palsy Service
2) Recruitment of people with facial palsy, not under the care of the Oxford Facial Palsy Service, through relevant web and social media pages (e.g. the Facial Palsy UK Facebook page)

Potential participants who have expressed an interest in the study will be provided with an information sheet and if still interested they will be invited to provide written consent (via an online consent form; Survey Hero). They will then be screened for eligibility using an online screening questionnaire (also Survey Hero). Participants recruited in Oxford Facial Palsy Service clinics will complete the screening questionnaire on the researcher's laptop during clinic or online at a later date if they wish to have more time to consider their participation in the study. Participants recruited on social media will be emailed a link to the screening questionnaire. Participants will have provided written consent for their email address to be shared with the research team.

Eligible participants will then be invited to complete baseline questionnaires:

People with facial palsy: Hospital Anxiety and Depression Scale; FACE-Q Satisfaction with appearance; FACE-Q Psychological function; FACE-Q Social function and Facial Disability Index.

Friends, relatives or partners: Hospital Anxiety and Depression Scale and Adult Carer Quality of Life Questionnaire.

Like the consent forms and screening questionnaires, baseline questionnaires will be completed online via Survey Hero.

Eligible participants will then be administered the relevant ITG. For eligible carers/relatives this will be the ITG entitled “Facial palsy: Advice for friends, family and partners”. For eligible participants with facial palsy, this will be determined by their score on the screening questionnaire. This process is outlined further in Section 7.2 ‘Screening and Eligibility Assessment’. Participants will then utilise the ITG over a period of four-to-six weeks. Half-way through the intervention period (after 2-3 weeks), they will receive an email reminding them to complete the ITG and will be provided a web-link to complete a questionnaire designed for the purpose of the current study measuring the participants’ ratings of acceptability and usability of the ITGs (participant satisfaction questionnaire) on Survey Hero.

At the end of the four-to-six week period, participants will be re-administered the baseline questionnaires (via web-link to Survey Hero), along with a questionnaire designed for the purpose of the current study measuring the participants’ ratings of acceptability and usability of the ITGs (participant satisfaction questionnaire). Participants will have a 2 week window to complete the final questionnaires after they have been sent to them at the end of the ITG trial period. If they do not complete the questionnaires in this window, they will be withdrawn from the study. Participants with facial palsy will also be re-administered the initial screening questionnaire. This will indicate whether the participant is eligible to complete a further ITG. If this is the case, then their post-intervention questionnaires will serve as a new baseline and the participant will be invited to complete the new ITG over a second four-to-six week period (followed by the same follow-up assessments as followed the first ITG). This process will occur up to a maximum of six times (reflecting the potential for a participant to trial all six ITGs). If they do not wish to complete further ITGs then the participant will be thanked for their involvement in the study and their involvement will be registered as ‘complete’. All participants will be provided with a separate email link to complete the relevant questionnaires at each stage (e.g. screening, baseline, 2-3 week satisfaction, 4-6 week final questionnaires). The email will also remind them of their unique ID number, for them to enter at the start of the questionnaires. This will help their responses to be matched with their previous responses.

We aim to trial the ITGs over a period of one year (July 2019 – May 2020). This will lead to the predicted sample sizes of 140 participants (120 with facial palsy, 20 per each of the 6 guides; 20 friends and family). This target is based on there being approximately 3000 people who have access to the Facial Palsy UK website. Given that approximately 1/3 people with facial palsy experience a significant level of distress (5); we hope that our ITGs would be relevant to, and accessible by, around 1000 people. 140 is therefore a conservative estimate of the number of participants that we will be able to recruit. Recruitment and completion will be monitored in case recruitment should be extended.

Participants recruited from OUH NHS Foundation trust will be provided with an information sheet during their clinic appointment with the Oxford Facial Palsy Service. Potential participants will then be given the option to either provide written consent in clinic using Survey Hero on the researcher’s laptop, or at a later stage (via weblink to Survey Hero consent form).

Participants recruited from social media will be provided with an information sheet via email and will provide written consent online using Survey Hero. Both people with facial palsy and their family members, friends and partners have access to Facial Palsy UK social media. Therefore both groups of participants can be recruited through this means.

6. PARTICIPANT IDENTIFICATION

6.1. Study Participants

Participants with a diagnosis of facial palsy, of any severity and aetiology or friends/relatives/partners of a person with facial palsy. In all instances participants will be aged 18 years or older.

6.2. Inclusion Criteria

Participant with Facial Palsy:

- Participant is willing and able to give informed consent for participation in the study.
- Aged 18 years or above.
- Current diagnosis of facial palsy, of any severity or aetiology.
- Participants experience one or more psychosocial difficulties related to facial palsy 'all the time' or 'a lot of the time', as assessed by a screening questionnaire (outlined in further detail in Section 7.2)

Participant who is a friend, family member or partner of someone with facial palsy:

- Participant is willing and able to give informed consent for participation in the study.
- Aged 18 years or above.
- Is a friend, family member or partner of an adult with facial palsy, of any severity or aetiology.
- Participants experience psychosocial difficulties related to supporting someone with facial palsy, as assessed by participant responding 'all the time' or 'a lot of the time' to one or more questions on a screening questionnaire (outlined in further detail in Section 7.2)

6.3. Exclusion Criteria

The participant may not enter the study if ANY of the following apply:

Participant with Facial Palsy:

- The participant is not in within the target age range (e.g. under the age of 18 years).
- They are not an individual with a current diagnosis of facial palsy.
- They do not speak enough English to understand the questionnaires or ITGs.

- They do not meet eligibility on the screening questionnaire (i.e. they 'never' or 'only occasionally' experience psychosocial difficulties associated with facial palsy (see section 7.2 Screening and Eligibility Assessment).

Participant who is a friend, family member or partner of someone with facial palsy:

- The participant is not in within the target age range (e.g. under the age of 18 years).
- They are not a friend, family member or partner of an adult with a current diagnosis of facial palsy.
- They do not speak enough English to understand the questionnaires or ITG.
- They do not meet eligibility on the screening questionnaire (i.e. they 'never' or 'only occasionally' experience psychosocial difficulties associated with supporting someone with facial palsy (see section 7.2 Screening and Eligibility Assessment).

Because participants will be using a unique ID number, it will not be possible for them to complete the screening questionnaire again, if their initial results indicate that they are ineligible. This is in order to prevent people from attempting screening multiple times to attempt to meet eligibility criteria.

Participants with facial palsy will not be matched with participants who are friends, family or a partner. Therefore, participants with facial will be eligible to participate, even if a friend, family member or partner does not participate. Likewise, a friend, family member or partner will be eligible to participate even if the person with facial palsy does not participate.

7. STUDY PROCEDURES

7.1. Recruitment

The participants in this study will be individuals with facial palsy and/or their family members/carers. They will be recruited by two means:

1) **Recruitment at Oxford Facial Palsy Service clinic appointments.** A member of the research team, who will also be a member of the care team, will approach eligible patients and/or friends or relatives during their clinic appointment. Given that all patients with facial palsy are eligible to take part in the study, it will not be necessary to review medical records prior to clinic to identify eligible participants. All potential participants will be provided with an information sheet, and opportunity to ask questions about the information sheet, at their clinic appointment.

   Interested participants will provide written consent via completion of an online Consent Form (via Survey Hero). This will either be done in clinic on the researcher's laptop, or if patients would like more time consider their involvement this can be done remotely online via Survey Hero.

They will be given a signed copy of their completed consent form. Participants who have consented will then complete an online screening questionnaire (again either in clinic or remotely). If eligible, participants will complete baseline questionnaires via Survey Hero. Upon completion of questionnaires they will be sent the relevant ITG.

For potential participants who are the friend, family member or partner of someone under the care of the Oxford Facial Palsy service, the process will be the same as above, with participants who are a friend, family member or partner providing informed consent prior to completion of screening questionnaires.

2) **Online recruitment, including social media.** The United Kingdom's leading facial palsy charity, Facial Palsy UK, has agreed to support recruitment for the current study through their platforms, including their Facebook page and research emailing lists. Advertisements will include the contact details for the lead researcher and interested participants will be invited to email the lead researcher for further information about the research project, including the information sheet. Once the participant has read the information sheet and indicated that they are keen to take part in the study they will be emailed a link on Survey Hero to complete an online consent form. They will be provided an electronic copy of their completed consent form. If they consent to take part they will then be sent a link to an online screening questionnaire. If eligible, they will then be sent a link to complete baseline questionnaires. Upon completion of questionnaires, they will be sent the relevant ITG. They will be sent either a physical copy in the post or an electronic copy via email (as indicated during completion of the relevant section of the Survey Hero baseline questionnaires).

   Advertisements will only directly target people with facial palsy themselves, rather than friends and relatives, with people with facial palsy being invited to take part and/or to nominate a friend or relative to take part.

Researchers will only be recruiting participants from within the United Kingdom.

7.2. Screening and Eligibility Assessment

All interested participants recruited from the Oxford Facial Palsy Service will be given an information sheet during their clinic appointment. Participants recruited through social media will be sent the information sheet via email if they have contacted the lead researcher in response to advertisement. Once participants have provided consent (see section 7.3), a member of the research team will send interested participants a link to an online screening questionnaire. This will be completed remotely for participants recruited online and online on a laptop during clinic for participants attending the Oxford Facial Palsy Service clinic. Alternatively, if participants recruited in clinic wish to have more time to consider whether or not to participate, they will be able to complete online screening (and subsequent baseline assessments) remotely online.

Screening:

For potential participants who are friends or relatives of individuals with a diagnosis of facial palsy, this involves answering two questions in relation to supporting someone with facial palsy:

1) Supporting someone with facial palsy has an impact on my own wellbeing.

2) I am having difficulties supporting someone with facial palsy.

There are 5 potential responses to each question: all the time; a lot of the time; only occasionally; never or N/A. If a potential participant responds ‘only occasionally’, ‘all the time’ or ‘a lot of the time’ to one or both of the screening questions then they are eligible to complete the friends, family or partner ITG.

For potential participants with a diagnosis of facial palsy, the ITG that participants first receive will be based on their response to six statements, each pertaining to a different ITG topic:

1) I have developed facial palsy in the last six months and am having difficulties coping with the condition **(ITG = Facial palsy: coping with the early stages)**
2) I have difficulties managing staring or comments and questions about my facial palsy **(ITG = Facial palsy: coping with comments, questions and staring)**
3) My facial palsy makes it difficult for me to communicate as confidently as I’d like **(ITG = Facial palsy: communicating with confidence)**
4) I feel anxious about having facial palsy **(ITG = Facial palsy: managing anxiety)**
5) I feel low or miserable about having facial palsy **(ITG = Facial palsy: managing your mood)**
6) Facial palsy affects how I feel about myself (self-esteem) **(ITG = Facial palsy: building your self-esteem)**

Participants are invited to rate each statement according to how frequently they experience each difficulty. There are 5 options: all the time; a lot of the time; only occasionally; never or N/A. Participants are eligible to complete ITGs if they have rated having difficulties relating to the topic of the ITG ‘all the time’ or ‘a lot of the time’. Participants will also be asked to rank the six statements in order of how much of a concern they are for them (1 = most important concern, 6 = least important concern). If participants are eligible to complete multiple ITGs (i.e. they rate experiencing difficulties ‘all the time’ or ‘a lot of the time’ for multiple topics), then they will complete ITGs in order of how much of a concern that area is for the participant. . They will be informed that they may be able to complete the next ITG that they are eligible for, at the completion of the 4-6 week trial period for their initial ITG.

At the completion of the 4-6 week trial period, participants will be invited to re-complete the original screening questionnaire and, if eligible (e.g. they still experience difficulties on one of the remaining topics ‘all the time’ or ‘a lot of the time’), will be invited to trial the next ITG. If they do not wish to complete further ITGs then the participant will be thanked for their involvement in the study and their involvement will be registered as ‘complete’

Participants who do not meet eligibility criteria will be thanked for their interest in the study and signposted to the Facial Palsy UK website for general information and advice for how to best manage facial palsy:

Thank you for your interest in this study. Unfortunately you do not currently meet the inclusion criteria for this study. For further information and advice about managing facial palsy please visit facialpalsy.org.uk or contact your NHS facial palsy service.

The screening questionnaires will also ask potential participants to provide information about their (or their family member or relative's) facial palsy diagnosis/type and date of onset.

7.3. Informed Consent

Participants must personally sign and date the latest approved version of the Informed Consent form before any study specific procedures are performed. As permitted by 'eIDAS' Regulation (EU) Number 910/2014 framework for electronic signatures, this will be typewritten in Survey Hero (i.e. participants will type their name and select the day's date to confirm consent).

The consent process will identical for participants who are individuals with facial palsy and participants who are friends or relatives of someone with facial palsy.

Written versions of the Participant Information Sheet (physical copy to patients recruited from the Oxford Facial Palsy Service and pdf copy sent via email to participants recruited from Facial Palsy UK) and Informed Consent (presented on Survey Hero) will be presented to the participants detailing no less than: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; the known side effects and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information, and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator.

The electronic copy of the signed Informed Consent will be exported to PDF, printed, signed and dated by the Principal investigator and then scanned/emailed to the participant. The original signed form will be retained at the study site.

For participants recruited in OUH clinics a copy of the signed consent form will also go in the medical notes.

7.4. Baseline Assessments

The following questionnaires will be administered via Survey Hero once participants have read the information sheet and met eligibility criteria. This will be completed online remotely for participants recruited via Facial Palsy UK (social media, website and mailing list) and online on a laptop during clinic for participants attending the Oxford Facial Palsy Service clinic (or remotely via Survey Hero if this is their preference).

Primary Objective
To evaluate the effectiveness of Information and Therapy guides at improving the psychosocial wellbeing of people with a diagnosis of facial palsy

This will be assessed by the change in an individual's self-report questionnaires before and after a four-to-six week intervention, using one of six information and therapy guides (the guide that they are given will be determined by their responses on a screening questionnaire). The questionnaires used will be:

Hospital Anxiety and Depression Scale (15): A 14-item scale with two seven-item subscales looking at anxiety and depression. A score equal-to-or-lower-than 7 on a subscale falls below the clinical cut-off, a score of 8-10 indicates probably clinically significant anxiety or depression, while a score of 11 or more indicates clinically significant anxiety or depression. It is well validated in the physical health population, excluding somatic symptoms of anxiety and depression that may overlap with symptoms of a physical health condition (15). It has been shown to have good test-retest reliability (= .70 to .84; 16).

FACE-Q Satisfaction with appearance (17): A nine-item scale assessing an individual's concerns regarding their facial appearance. The higher the score, the greater the patient's dissatisfaction with their appearance, with a highest possible score being 32. This measure has been demonstrated to have good reliability within a plastic surgery population (17).

FACE-Q Psychological function (18): This 11-item scale measures psychological wellbeing using a series of positively worded statements, with participants invited to rate how much they agree/disagree with each statement. A high score (maximum = 40) indicates greater psychological wellbeing. This measure has been validated within a clinical setting and has been shown to have a Cronbach alpha of .96, indicating very good internal consistency (18).

FACE-Q Social functioning (18): Like the FACE-Q psychological function scale, participants are provided with a series of positively worded statements. In this scale there are 9 statements and they pertain to measuring social functioning. Just as with the psychological function scale, the social functioning scale has a Cronbach alpha of .96 and has been shown to have good convergent and discriminant construct validity.

Facial Disability Index (19): A 10-item self-report measure of physical and social function in people with facial palsy. Both the physical (=.88) and social (=.83) subscales have been shown to have good internal consistency and construct validity (19). Each scale is scored out of 100 (100 = high function).

This measure of facial function will allow the researchers to control for improvement or decline in facial palsy symptoms when assessing the impact of the ITG's on psychological wellbeing.

Note: the friends/relatives of participants with facial palsy are not required to complete questionnaires, unless they themselves are actively participating in the study (i.e. are trialling the family, friend or partner ITG)

Secondary Objectives
To evaluate the effectiveness of Information and Therapy guides at improving the psychosocial welling of friends and relatives of people with a diagnosis of facial palsy

This will be assessed by the change in friend’s/relative’s self-report questionnaires before and after a four-to-six week intervention using the information and therapy guide: Facial palsy: Advice for friends, relatives and partners of people with facial palsy.

The outcome measures used will be the **Hospital Anxiety and Depression Scale** (described above), along with the **Adult Carer Quality of Life Questionnaire** (20). This is a 40-item self-report scale that measures the overall quality of life for adult carers. Subscale scores include: support for caring; caring choice; caring stress; money matters; personal growth; sense of value; ability to care and carer satisfaction. Scores fall on a 0-120 scale, with higher scores indicating better quality of life.

7.5. Subsequent Visits

Participants will be followed up at two different time points:

After 2-3 weeks:

Participants will be contacted via email to remind them to complete their current ITG. The will also be sent a link to an online questionnaire, pertaining to their ratings of acceptability and usability of the ITG (participant satisfaction questionnaire; in line with the **Tertiary Objective:** To evaluate the acceptability and usability of Information and Therapy guides for people with facial palsy and/or their friend or relative).

After 4-6 weeks:

Participants will be contacted via email to thank them for completing their current ITG. They will be sent a link to an online questionnaire, pertaining to their ratings of acceptability and usability of the ITG (participant satisfaction questionnaire; in line with the **Tertiary Objective:** To evaluate the acceptability and usability of Information and Therapy guides for people with facial palsy and/or their friend or relative).

Participants will also be sent a web link to re-complete their baseline assessments (in line with the **Primary** and **Secondary Objectives**).

Finally, participants with facial palsy will be invited to re-complete the initial ITG screening questionnaire, to determine whether they might be eligible to complete a further ITG. If eligible, consent will be sought again and the above process will repeat (up to a maximum of 6 times, once for each ITG). Since participants who are friends/relatives of people with facial palsy will only have one ITG available to them, they will not be provided with the opportunity to complete a further ITG.

7.6. Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw from the study at any time. In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Withdrawal of Consent (withdrawn participants will be replaced and their data will be excluded from analysis)

7.7. Definition of End of Study

The end of study is the date of the completion of the last ITG (and associated questionnaires) of the last participant.

8. INTERVENTIONS

The intervention piloted in the current study will be the completion of Information and Therapy Guides. We have developed seven self-guided information and therapy guides (ITGs), for people with facial palsy and/or their friends or relatives, using evidence-based interventions such as cognitive behavioural therapy, social skills training and acceptance and commitment therapy:

1) **Facial palsy: Coping with the early stages.** Given the lack of surgical treatment/Botox available in the early stages of facial palsy, it was deemed important to produce an ITG focusing on helping patients to cope with the early stages of their condition.
2) **Facial palsy: Coping with comments, questions and staring.** Due to research (e.g. 6) indicating the impact of facial palsy on people's social skills we decided to produce two guides focussing on improving the social skills of this population. This first guide helps people to learn ways of managing challenging social situations and to explain their facial palsy to others in a confident way.
3) **Facial palsy: Communicating with confidence.** The second of the guides focusing on improving social skills of people with facial palsy. Given the significant role of facial expression during social interactions, and the difficulties that people with facial palsy often having in producing facial emotional expressions, this guide helps people with facial palsy to identify ways in which they can use verbal and non-verbal communication to communicate in a confident way.
4) **Facial palsy: Managing anxiety.** Facial palsy often has a significant impact on an individual's levels of anxiety (5). This guide integrates CBT and acceptance and commitment therapy techniques to help patients with facial palsy to manage their anxiety, particularly with regards to their appearance and social situations.
5) **Facial palsy: Managing your mood.** Nearly 1 in 3 people with facial palsy experience significant levels of depression (5). This guide uses principles of CBT to help people with facial palsy to manage their mood.
6) **Facial palsy: Building your self-esteem.** Low self-esteem is a significant predictor of distress amongst individuals with facial palsy (10) and this guide, drawing upon CBT and acceptance and commitment therapy, focuses on helping people with facial palsy to build their confidence and self-esteem.

7) **Facial palsy: Advice for friends, family and partners.** At the Oxford Facial Palsy Service we are aware that facial palsy not only has an impact on people with facial palsy, but also the wellbeing of their friends and family. This guide offers advice to friends and family in order to help them look after their own wellbeing, as well as maximise the support that they provide for the person with facial palsy.

This current study aims to pilot the use of these guides in order to assess their effectiveness at improving the psychosocial wellbeing of people with facial palsy and their friends and family. Eligible participants will complete a set of baseline measures prior to trialling the use of a relevant ITG over a period of four-to-six weeks. After the four-to-six weeks, participants will re-complete the measures completed at baseline, along with a questionnaire assessing the usability and acceptability of the ITGs.

9. STATISTICS AND ANALYSIS

9.1. Description of Statistical Methods

This study will follow a pre-post design and as such will use paired t-tests to observe whether a statistically significant change has occurred on each of the outcome measures, for each ITG. Descriptive statistics will also be provided (e.g. mean scores on each outcome measure at baseline).

9.2. The Number of Participants

We aim to trial the ITGs over a period of two years (May 2019 – May 2021). This will lead to the predicted sample sizes of 140 participants (120 with facial palsy, 20 per each of the 6 guides; 20 friends and family). This target is based on there being approximately 3000 people who have access to the Facial Palsy UK website. Given that approximately 1/3 people with facial palsy experience a significant level of distress (5); we hope that our ITGs would be relevant to, and accessible by, around 1000 people. 140 is therefore a conservative estimate of the number of participants that we will be able to recruit. As this is an initial feasibility study, a power analysis was not conducted for the purposes of this study.

9.3. Analysis of Outcome Measures

A pre-post design will be used to determine whether the use of ITGs lead to a significant improvement in the psychosocial wellbeing of people with facial palsy and or their friends and relatives, as measured by the Hospital Anxiety and Depression Scale, Face-Q – Social function (people with facial palsy only), Face-Q – Psychological function (people with facial palsy only), Face-Q – Appearance-related psychosocial distress (people with facial palsy only) and the Facial Disability Index (people with facial palsy only). This change will be measured for each individual ITG, using paired-samples t-tests. The Facial Disability Index can also be used to control for improvement in facial palsy symptoms, when assessing the impact of ITGs on scores on measures of psychological wellbeing. In the instance of a significant change in facial palsy symptoms being observed, separate ANCOVAs will be used, with Facial Disability Index score being used as a covariate and scores on individual measures of psychosocial wellbeing serving as within-subjects factors.

10. DATA MANAGEMENT

10.1. Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

10.2. Data Recording and Record Keeping

None of the study documents besides the identification log (and consent forms) will contain any identifiable data.

Participants are assigned a study ID and this will be used on all online questionnaires, study documents and the database which will contain no identifiable data, they will only be identifiable on the ID log linking the ID number and their personal information.

The log of study IDs will be kept electronically and separately from participant data and will only be accessible by members of the research team.

Electronic copies of consent forms will be kept in password protected file, separate to completed questionnaires, which will be kept securely and separately in a password protected file.

Hard copies of consent forms will be kept in the Study Master File, separate to completed questionnaires, which will be kept securely and separately to the Study Master File. These will be in a locked filing cabinet in the Russell Cairns Unit, Level 3 West Wing, John Radcliffe Hospital.

Questionnaire data will be transferred to an excel sheet and SPSS datasheet.

These databases, and ID log, will be kept separately on a password protected database/spreadsheet stored on NHS servers.

The database will be tested at regular intervals to ensure accuracy. This will be done by the lead researcher selecting one participant at random, to ensure that the data has been entered accurately.

The Study Master File and anonymised research data will be kept for 5 years.

Contact details for parents who'd like to receive a copy of the results will be stored for 12 months and kept securely and separately to any anonymised research data.

Survey Hero is GDPR compliant.

11. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

12. ETHICAL AND REGULATORY CONSIDERATIONS

12.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

12.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

12.3. Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), and HRA for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

12.4. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required) host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

12.5. Participant Confidentiality

The study staff will ensure that the participants' anonymity is maintained. The participants will be identified only by a participant ID number on all study documents and any electronic database. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so. No identifiable data will be published.

12.6. Expenses and Benefits

Since data collection will take place at routine clinic appointment or via email/web-based survey, travel expenses will not be reimbursed.

12.7. Other Ethical Considerations

The questionnaires used in this study include topics that may be sensitive for certain participants. For example, certain questions ask about the participant's mood and anxiety. In particular, the Hospital Anxiety and Depression Scale will indicate whether participants are experiencing clinically significant anxiety and/or depression. If participants report clinically significant anxiety and/or depression, then the lead researcher will contact the participant on the telephone (or talk to the participant if meeting face-to-face in clinic) to inform them of that their score is indicative of elevated levels of anxiety and/or depression and that we recommend that they contact their GP to discuss this further. We will also provide emergency/out of hours information (if it is out of hours and your GP surgery is closed, dial 111 if they wish to speak with a GP. If it is an emergency situation call 999.)

The consent form contains information for participants informing them that the research team will not be providing psychological treatment for participants, beyond the use of ITGs, and as such participants should contact their GP, rather than the research team, if they are concerned about their psychological wellbeing.

13. FINANCE AND INSURANCE

13.1. Funding

This project is funded by the VTCT foundation. The VTCT Foundation awarded £61,383.88 for use over a 30 month period. This grant covers the salary for the lead researcher (0.4 wte), as well as research costs, design and printing costs and conference/travel costs.

13.2. Insurance

NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical research study as a result of negligence on the part of a member of the study team this liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. The Oxford University Hospitals NHS Foundation Trust, therefore, cannot agree in advance to pay compensation in these circumstances.

In exceptional circumstances an ex-gratia payment may be offered.

14. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the VTCT Foundation. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

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16. APPENDIX A: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made

List details of all protocol amendments here whenever a new version of the protocol is produced. This is not necessary prior to initial REC submission.

APPENDIX B – FLOW CHART