

PARTICIPANT INFORMATION SHEET FOR PARENTS

Title of Study: Feasibility of an online Compassion Focused Therapy (CFT) intervention for children and young people (CYP) aged 14-18 with Type 1 Diabetes.

University of Surrey Ref: _____

PLEASE KEEP A COPY OF THIS INFORMATION SHEET FOR YOUR RECORDS

Section: Taking Part

Introduction

We would like to ask for your support and involvement with our research study. Please read the following information carefully. We are looking for children and young people aged between 14 and 18 years old to take part in our research looking at whether an online psychology intervention (called Compassion Focussed Therapy) can be helpful in supporting the mental and physical health of those living with Type 1 Diabetes (T1D).

What is the purpose of the study?

We are interested in researching whether online, 10-minute videos that includes information and exercises from Compassion Focused Therapy helps improve scores on self-compassion, quality of life and reduces time in range blood glucose levels.

Who is responsible for this study?

This study is the responsibility of Arun Sahni (Trainee Clinical Psychologist) at the University of Surrey being supervised by Professor Chrissie Jones.

Why has my child been invited to take part?

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Your child has been asked to take part in this research project as they meet all the below requirements:

- Children or young person aged 14-18 with a diagnosis of T1D.
- They are able to commit to viewing online videos every other day for the period of three weeks (precisely 23 days from session 1 to session 12).
- Able to understand English language for both viewing videos and reading questionnaires as part of the research.
- Have access to technology to view video sessions (desktop computer, laptop, smartphone or tablet device).
- Access to a quiet and confidential space in home environment.
- They have an established diagnosis of T1D (longer than 12 months).
- They agree to participate in the study.

Do they have to take part?

No, they do not need to take part in this study if they do not want to. However, if they do agree to participate, we will ask them and yourselves to sign a consent form. If your child does end up taking part and decides later that they want to leave, they will be able to do this. Please do not worry, this will not affect their care from the Paediatric Diabetes service and there will be no actions taken against them.

What will happen to my child if they decide to take part?

If you agree to allow your child to take part in our research, they will be put into one of two different groups. If they are put into the 'experimental' group we will then ask them to watch 12 videos over 23 days (they will need to watch one video every two days). Each video will last approximately 10 minutes and we will send them the links to watch on their own personal device. Your child can watch the videos in their own time and at home, so long as they make sure they do watch them on the days required as this is essential to keep up with the schedule. However, if your child is put into the 'control' group they will not need to watch the videos but we will ask them to complete questionnaires at three different points in time. If your child is put in this group, we will provide them with the videos once the whole study is finished. People will be put into

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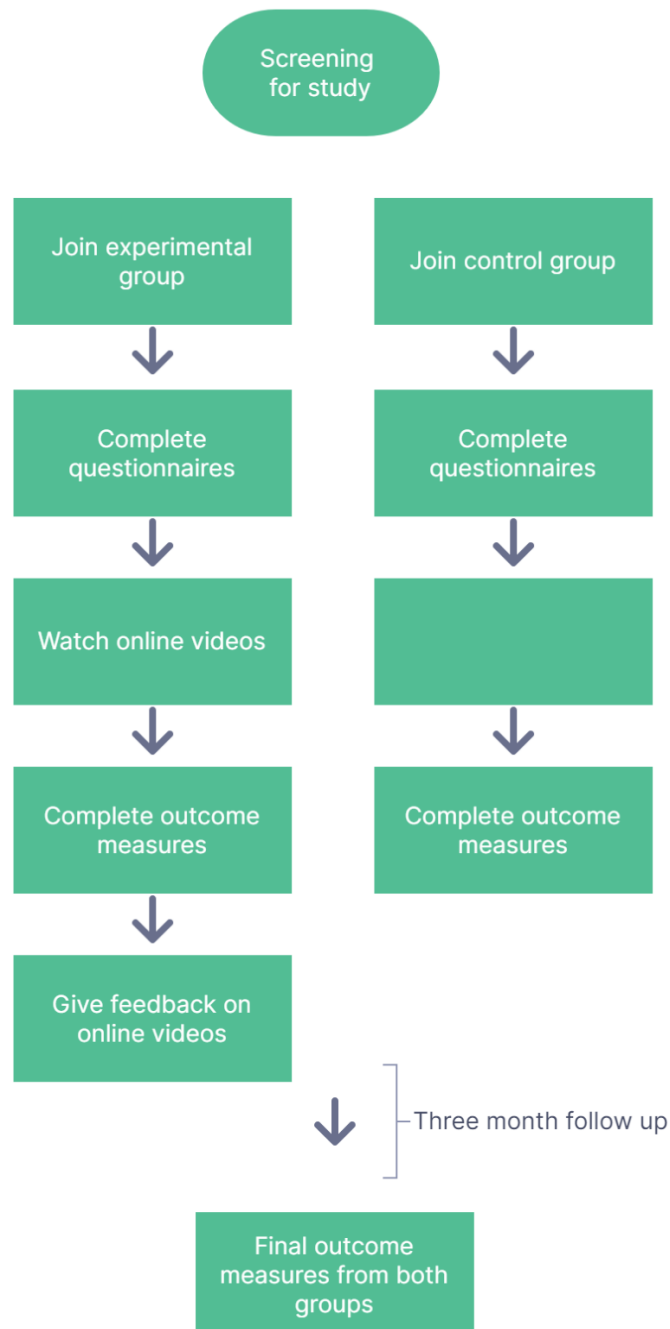
different groups by random selection. You can find a diagram below showing you how this process will go if your child decides to take part.

We will also be asking your children to complete some questionnaires before and after watching the videos, and then again one more time 3 months later. We will also ask them to report their blood glucose levels for both HbA1c and their time in range scores. We will request they report their time in range scores at the same time as the other questionnaires (baseline, post-intervention and 3 month follow up) whereas their HbA1c scores only from baseline to three month follow up. Finally, we would be interested in their feedback, specifically what their thoughts and impressions were of the style of videos and so will ask for this after they finish completing the course/watching all the videos. All questionnaires will be sent to complete via email.

What happens if I do not want my child to take part or if I change my mind later?

You are free to withdraw your child from the study at any time, without giving a reason. Anonymised data (data which doesn't have anything to identify them as an individual) collected up until the point they withdraw will be used in analysis, but no further data will be collected from them. They can withdraw from the study by getting in contact with a member of the research team whose details are below.

What will happen to my child if they do take part?



What are the possible benefits in taking part?

Those who take part may benefit from increasing their understanding of self-compassion and how to use the techniques to be more sensitive to moments of distress, self-blame or criticism. It is hoped that this study will be useful for children and young people involved in it, and to help increase our research knowledge base of how compassion focussed interventions can help young people with T1D. Everyone who is in the 'control group' for the duration of the study will also receive the online intervention at the end of the study.

Are there any potential risks involved?

When taking part in a psychological study there is always a chance that difficult feelings may arise. If for any reason you notice or learn that your child becomes distressed during the study and needs support, please do not hesitate to contact a member of the research team. Alternatively, if this distress becomes an immediate emergency please call the emergency services of which you can find listed at the bottom of this information sheet (please see below). You can also speak to your diabetes team if you experience any difficult feelings as a consequence of the research study.

How is the project being funded?

This research is a student project as part of a Doctorate in Clinical Psychology and the information we gather will be towards this qualification. No external funding has been received for this research.

Will my child's participation be kept confidential?

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Your child's personal data will be accessed, processed and securely destroyed by members of the research team including the principal and co-investigators. In order to check that this research study is carried out in line with the law and good practice, it is possible that monitoring and auditing may be carried out by independent authorised individuals. Data collected during the study may be looked at by authorised individuals from the University of Surrey and from regulatory authorities, where it is relevant to them taking part in this research study. All will have a duty of confidentiality to you and your child as a participant and we will do our best to meet this duty. We will anonymise any documents or records that are sent from the University of Surrey, so that your child cannot be identified from them.

The data you provide will be anonymised and personal data will be stored securely and separately from the anonymised data. Your child's name and address will be removed from all of the documents used in the study, and they will be assigned a numerical code. Any data traced back by this code will be stored separately so you will not be identifiable. The research team may use direct quotes from the online surveys in a report of the study results, but these will all be completely anonymised and a unique identifier will be used instead of real names. Your child will also not be identified in any reports/publications resulting from this research study and so those reading them will not know who has contributed to the research study.

In certain exceptional circumstances where information arising from you child's participation indicates that they or others may be at significant risk of harm, the researcher may need to report this to an appropriate authority, in accordance with the UK General Data Protection Regulations (GDPR, 2018). This would usually be discussed with them first.

Examples of those exceptional circumstances when confidential information may have to be disclosed are:

- I (The researcher) believes your child is at serious risk of harm, either to themselves or others.
- I (The researcher) suspects another child may be at risk of harm.
- Your child poses a serious risk of harm to, or threatens or abuse others.
- As a statutory requirement e.g. reporting certain infectious diseases.
- Under a court order requiring the University of Surrey to divulge information.
- We are passed information relating to an act of terrorism.

Will my child's data be shared or used in future research studies?

There is no intention to use the data generated from this study in future studies.

What will happen to the results of the study?

All results from the study will be included in our analysis, which will give us an idea of how effective the online intervention is to help children and young people with T1D. We will put all this data together into a report that will be published, and we will provide to all participants and to the Paediatrics diabetes service once the study is complete. The research findings will also be disseminated as a peer-reviewed scientific article and conference presentation with published findings maintaining participant confidentiality and anonymity. We assure all participants that the results will be anonymised with all the reports published.

Who is organising and supporting/funding the study?

The study is being organised by researchers from the University of Surrey with the support and help from Southampton Children's Hospital who are a part of University Hospitals Southampton NHS Foundation Trust. We are not receiving any funding for this study, nor will we get paid any extra money.

Who has reviewed and approved of this study?

Before any research must go ahead, it is very important that it is assessed and approved by the Health Research Authority (HRA) and its Research Ethics Committee (REC). It is the job of this committee to safeguard the rights, safety, dignity and well-being of research participants. We have had our research approved by the Health Research Authority (HRA), Research Ethics Committee (REC) and the University Hospitals Southampton NHS Foundation Trust.

Section: Your personal data

What is personal data?

‘Personal Data’ means any information that identifies you as an individual. We will be collecting and using some of your child's personal data that is relevant to completing the study and this section describes what that means.

The information that we will collect will include your child's name and contact details which is regarded as ‘personal data’ and gender, ethnic origin, and your health (both physical and psychological) which is regarded as a ‘special category personal data’. We will use this information as explained in the ‘What is the purpose of the study’ section above.

Who is handling my personal data?

The University of Surrey, who has the legal responsibility for managing the personal data in this study, will act as the ‘Data Controller’ for this study. The research team will process your child's personal data on behalf of the controller and are responsible for looking after personal information and using it properly.

What will happen to my child's personal data?

As a publicly funded organisation, we have to ensure that when we use identifiable personal information from people who have agreed to take part in research, that this data is processed fairly and lawfully. The University of Surrey processes personal data for the purposes of carrying out research in the public interest and special category data is processed on an additional condition necessary for research purposes. This means that when you agree for your child to take part in this research study, we will use and look after the data in the ways needed to achieve the outcomes of the study.

Your child's personal data will be held and processed in the strictest confidence, and in accordance with current data protection regulations. When acting as the data controller, the University will keep identifiable information about your child for 10 years after the study has finished after which time any identifiers will be removed from the aggregated research data.

Your child's rights to access, change or move information are limited, as we need to manage personal information in specific ways in order for the research to be reliable and accurate. If you decide to withdraw your child from the study, we will not be able to withdraw data collected up to that point. We will only keep and use the minimum amount of information about them that we have already obtained in order to complete the study.

If you wish to make a complaint about how we have handled your child's personal data, you can contact our Data Protection Officer Suzie Mereweather who will investigate the matter (dataprotection@surrey.ac.uk). If you are not satisfied with our response or believe we are processing personal data in a way that is not lawful, you can complain to the Information Commissioner's Office (ICO) (<https://ico.org.uk/>).

You can find out more about how we use your information <https://www.surrey.ac.uk/information-management/data-protection> and/or by contacting dataprotection@surrey.ac.uk.

Section: Further information

What if you have a query or something goes wrong?

If you are unsure about something you can contact the research team for further advice using the contact details at the bottom of this information sheet.

However, if your query has not been handled to your satisfaction, or if you are unhappy and wish to make a formal complaint to someone independent of the research team, then please contact:

Assurance Team

Research, Innovation and Impact

University of Surrey

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Phone: +44 (0)1483 689110

Email: assurance@surrey.ac.uk

The University has in place the relevant insurance policies which apply to this study. If you wish to complain or have any concerns about any aspect of the way you have been treated during the course of this study, then you should follow the instructions given above.

Who can I contact if I have questions or want more information about this study?

If you have any concerns or questions, or you wish to find out more about the study, please contact the researcher from the below contact details:

Primary researcher name: Arun Sahni (Trainee Clinical Psychologist)

Primary researcher email address: a.sahni@surrey.ac.uk

Location:

University of Surrey

School of Psychology

Lewis Carroll building (AC)

Guildford

GU2 7XH

Name: Professor Christina Jones

Role: Professor in Clinical Psychology, Supervisor.

Email: c.j.jones@surrey.ac.uk

Please also visit our website at <https://www.surrey.ac.uk/school-psychology/research>.

If at any point during the study you or someone else is concerned about your health and wellbeing, please refer to the below support services:

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- Diabetes UK helpline number is 0345 123 2399. It is a dedicated diabetes helpline for all people with diabetes, their family or friends, and people who are worried they might be at risk.
- The Samaritans offer emotional support 24 hours a day - in full confidence. Call 116 123 - it's FREE.
- For free, confidential support, 24/7, text SHOUT to 85258. If you are struggling to cope and need to talk, trained Shout volunteers are available day or night.
- The Campaign Against Living Miserably (CALM) is leading a movement against suicide. You can talk to CALM about anything. The helpline and webchat are both open 5pm to midnight, 365 days a year.
- If your concerns relate to an immediate emergency or if someone's life is at risk or in danger, please call 999 or go to Accident and Emergency (A&E) now.

Thank you for reading this information sheet and for considering taking part in this research.