Imperial College Healthcare NHS Trust

Imperial College London

HYPE

Avoidance of Hyperglycaemia in people with Type 1 Diabetes

V1.3

MAIN SPONSOR:	Imperial College London
FUNDERS:	Imperial Charity Pre-doctoral Fellowship
STUDY COORDINATION CENTRE:	Imperial College London

IRAS Project ID:	288601
REC reference:	20/SW/0174

Protocol authorised by:

Name & Role	**Date**	**Signature**

Study Management Group

Chief Investigator:	Prof Nick Oliver
Co-investigator:	Dr Vicky McKechnie
Statistician:	Dr Ian Godsland
Research Collaborator:	Professor John Fox
Study Management:	Dr Vicky McKechnie

Clinical Queries

Clinical queries should be directed to Prof Nick Oliver who will direct the query to the appropriate person.

Sponsor

Imperial College London is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

Research Governance and Integrity Team
Imperial College London and Imperial College Healthcare NHS Trust
Room 215, Level 2, Medical School Building
Norfolk Place
London, W2 1PG
Tel: **0207 594 9459/ 0207 594 1862**
http://www3.imperial.ac.uk/clinicalresearchgovernanceoffice

This protocol describes the HYPE study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Frame Work for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

Table of Contents **Page No**

1.	INTRODUCTION	6~~7~~
1.1	BACKGROUND	6~~7~~
2.	STUDY OBJECTIVES	7~~8~~
3.	STUDY DESIGN	8~~9~~
3.1	STUDY OUTCOME MEASURES	8~~9~~
4.	PARTICIPANT ENTRY	9~~10~~
4.1	PRE-REGISTRATION EVALUATIONS	9~~10~~
4.2	INCLUSION CRITERIA	9~~10~~
4.2	EXCLUSION CRITERIA	9~~10~~
4.3	WITHDRAWAL CRITERIA	9~~10~~
5.	ADVERSE EVENTS	10~~11~~
5.1	DEFINITIONS	10~~11~~
5.2	REPORTING PROCEDURES	10~~11~~
6.	ASSESSMENT AND FOLLOW-UP	12~~13~~
7.	STATISTICS AND DATA ANALYSIS	16~~17~~
8.	REGULATORY ISSUES	18~~19~~
8.1	ETHICS APPROVAL	18~~19~~
8.2	CONSENT	18~~19~~
8.3	CONFIDENTIALITY	18~~19~~
8.4	INDEMNITY	18~~19~~
8.5	SPONSOR	18~~19~~
8.6	FUNDING	19~~20~~
8.7	AUDITS	19~~20~~
9.	STUDY MANAGEMENT	20~~21~~
10.	PUBLICATION POLICY	21~~22~~
11.	REFERENCES	22~~23~~
12.	APPENDICES	23~~24~~

APPENDIX 1. STUDY QUESTIONNAIRES (ATTACHED SEPARATELY) 232324

APPENDIX 2. DATA FLOW MAPPING 242425

GLOSSARY OF ABBREVIATIONS

T1D	Type 1 Diabetes

KEYWORDS

Diabetes Mellitus, Hyperglycaemia,

STUDY SUMMARY

TITLE	Avoidance of Hyperglycaemia in people with Type 1 Diabetes
DESIGN	Non-interventional, Cross-sectional study
AIMS	To assess how problematic fear of hyperglycaemia is in people with T1D
OUTCOME MEASURES	Quantitative and qualitative measures
POPULATION	n=up to 350
ELIGIBILITY	Diagnosis of T1D for at least 6 months
DURATION	1 hour per participant, 9 months total study duration. Participants who participate in the interview study (n=16) will undergo an additional 90 minute interview.

1. INTRODUCTION

1.1 Background

Approximately 400000 people in the UK have T1D (1). Self-management of T1D involves a challenging regimen requiring monitoring of blood glucose levels several times per day and multiple daily insulin injections. People living with T1D can experience a number of psychological difficulties, including feeling burned out, fear of high and low blood glucose levels, adjustment to diabetes-related complications, and problems around eating. Higher levels of diabetes-related distress are associated with a higher HbA1c (2,3) which is associated with increased risk of micro- and macro vascular diabetes-specific complications. The importance of psychological support for people with T1D is increasingly recognised (4), and both published and Imperial data demonstrate the importance of psychological support (5,6).

Published data describe the assessment and consequences of fear of hypoglycaemia in people with T1D (7,8). Hypoglycaemia fear is associated with a higher HbA1c and increased risk of diabetes-related complications. The Hypoglycaemia Fear Survey (HFS-ii) (9,10) is a valid and reliable tool for assessment used in routine clinical care, including in the psychological assessment and intervention outcome data for the Imperial T1D Psychology service. NICE guidelines (11) reference fear of hypoglycaemia as a barrier to achieving HbA1c targets and recommend continuous glucose monitoring for those with extreme fear.

There is, however, little research about fear, or problematic avoidance, of hyperglycaemia in T1D (12). It is, however, a problem that we see in the T1D clinics at Imperial, often with significant adverse consequences. As well as high levels of distress, it is associated with recurrent hypoglycaemia exposure, eroded hypoglycaemia awareness and increased healthcare utilisation (13). More problematically, fear of hyperglycaemia may not be identified, as the HbA1c is often at, or below, target.

1.2 Rationale for current study

Fear of hyperglycaemia represents a gap in knowledge and has implications for clinicians' skills in recognising this problem, and for understanding how best to support the people who experience it.

2. STUDY OBJECTIVES

Primary Objective

Assess how problematic fear of hyperglycaemia is in T1D

Secondary Objectives

Identify whether fear of hyperglycaemia is associated with any clinical factors

Identify the psychological factors that underpin fear of hyperglycaemia

Assess how fear of hyperglycaemia affects self-management of T1D

3. STUDY DESIGN

Non-interventional, cross-sectional questionnaire study in adults with T1D

1 hour per participant, 9 months total

n=up to 350 participants total

Sub study of approximately n=16 participants for semi-structured interviews (1.5 hours per participant)

3.1 Study Outcome Measures

1. Quantitative data:
    a. Hyperglycaemia avoidance scale (HAS)
    b. Hypoglycaemia fear survey (HFS-II)
    c. Problem areas in diabetes scale 5 (PAID-5)
    d. Patient health questionnaire (PHQ-9)
    e. Generalised anxiety disorder scale (GAD-7)
    f. State trait anxiety inventory (Trait subscale)

2. Descriptive data – semi-structured interview

Additional baseline participant data to be pulled from Cerner/via participant survey:

- Age
- Ethnicity
- Length of diabetes
- Current diabetes treatment
- Diabetes complications: nephropathy, neuropathy, retinopathy, cardiovascular disease
- Recent HbA1C
- Other medical conditions
- Other medications
- Hypos – frequency/severity
- Blood glucose monitoring - method and frequency

4. PARTICIPANT ENTRY

4.1 Pre-registration evaluations

Potential participants will be identified by the clinical diabetes team from the list of people who attend the diabetes clinics at Imperial College Healthcare NHS Trust. Participants with type 1 diabetes who do not attend an Imperial College Healthcare NHS Trust diabetes clinic who have consented to be contacted by the Imperial diabetes research team for research purposes will also be invited to participate in the study.

Of the participants who are enrolled in the study, and who have consented to be contacted for an interview, the research team plans to select approximately 16 participants to take part in the qualitative interview. Participants will be selected based on clinician identification and participant self-identification of fear of hyperglycaemia, as well as from a dynamic list of those in the upper quadrant of recorded scores on the Hyperglycaemia Avoidance Scale.

4.2 Inclusion Criteria

- Previous diagnosis of Diabetes Mellitus of at least 6 months
- Aged 18 or above

4.2 Exclusion Criteria

- Inability to understand and write in the English language
- Unable to participate due to other factors, as assessed by the Chief Investigators
- Pregnant women

4.3 Withdrawal criteria

- Loss of capacity to give informed consent
- Investigator initiated discontinuation of study due to participation concerns

Withdrawal will be immediate, and participants will be followed up in the appropriate out-patient diabetes clinic at their usual appointments. If a participant withdraws no more data will be collected on them but identifiable data already collected with consent will be retained and used in the study.

If a participant, who has given informed consent, loses capacity to consent during the study the participant will be withdrawn from the study. Identifiable data already collected with consent will be retained and used in the study. No further data would be collected or any other research procedures carried out on or in relation to the participant.

5. ADVERSE EVENTS

5.1 Definitions

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*
- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

5.2 Reporting Procedures

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

5.2.1 Non serious AEs

All such events, whether expected or not, should be recorded.

5.2.2 Serious AEs

An SAE form should be completed and faxed to the Chief Investigator within 24 hours. However, relapse and death due to diabetes mellitus, and hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to the Cornwall and Plymouth REC where in the opinion of the Chief Investigator, the event was:

- 'related', i.e. resulted from the administration of any of the research procedures; and
- 'unexpected', i.e. an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator must also notify the Sponsor of all SAEs.

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

Contact details for reporting SAEs
jrco@imperial.ac.uk
CI email (and contact details below)
Fax: 020 7594 2432, attention Prof Nick Oliver
Please send SAE forms to: Diabetes, Endocrinology and Metabolism Medicine, Imperial College London, Room G3 Medical School Building, St Mary's Campus, Norfolk Place, London W2 1PG
Tel: 020 7594 2460 (Mon to Fri 09.00 – 17.00)

6. ASSESSMENT AND FOLLOW-UP

The main study will consist of completing a survey and some questionnaires. This should take no more than 1 hour to complete by the participant at a time and location convenient to them. Participants will be invited to consent to be contacted for the optional sub-study which will be described later in this section.

All eligible participants will be identified by the clinical care team. A list of potential participants will be identified from the database of all people who attend the diabetes clinics at Imperial College Healthcare NHS Trust (subsequently known as the participant database). Additionally, eligible participants from the list of non-Imperial research consenters will also be contacted about the study.

Potential participants will be contacted in one of three ways by the clinical team:

a) Participants whose emails are available on Cerner or who are not Imperial patients but have consented to contact for research will be contacted by email by a member of the research team. The email will include the PIS and a link to Qualtrics (an online data collection platform which is supported by the college). Informed consent will be taken via this platform with questionnaires to follow (only accessible if participant has consented to all clauses and signed electronically). Participants will be able to arrange a phone call with the research team to discuss any issues or concerns before signing the consent if they wish. Participants who attend clinics at Imperial College Healthcare NHS Trust will be provided with a unique code to enable researchers to link their questionnaire data with their medical records. This will be different to the study code and which will be assigned to participants after consent in order of enrolment.
b) For potential participants whose emails are not available or who prefer a hard copy approach, study packs, including the patient information sheet, consent form and questionnaire will be sent by post for completion at home, and returned in a pre-paid addressed envelope to the research team.
c) Patients who are seen in clinic by the diabetes team will be approached by their clinical team about participating in the study. Those who are interested will then be provided with a consent form and study questionnaire which can either be completed and returned to the research team whilst in the clinic or taken home and returned in a stamped addressed envelope at the participant's convenience.

Of the participants who are enrolled in the study, and who have consented to be contacted for an interview, the research team plans to select approximately 16 participants to take part in the qualitative interview. Participants will be selected based on clinician identification and participant self-identification of fear of hyperglycaemia, as well as from a dynamic list of those in the upper quadrant of recorded scores on the Hyperglycaemia Avoidance Scale.

Participants will be advised that questionnaires should be returned by the end of the study for inclusion in the study analysis.

Within the patient information sheet there will be contact details for the research team, should the participant wish to discuss the study and obtain any further details.

Once returned, the pseudonymised questionnaire data will be recorded in a password encrypted database on an Imperial College Healthcare NHS Trust or Imperial College London computer (subsequently known as the results database). Informed consent will be filed in the trial master file.

Once informed consent has been provided, the research team will then review the electronic health records of those Imperial College Healthcare NHS Trust participants who have consented to record biochemical data, medical history. Other baseline data e.g. demographics will be collected via a participant survey which will be mailed alongside questionnaires. This data will be recorded in pseudonymised form in the results database. Data from Qualtrics will be downloaded in a PDF format on either an ICL or ICHT computer and printed for hard copy records. Questionnaire scoring data will be pulled from Qualtrics in a pseudonymised format and saved on either an ICL or ICHT computer within an encrypted, password protected document.

In all cases, no samples are taken and all data will be pseudonymised. No follow up outside of usual care will be provided.

If participants wish to see their questionnaire scores, they will be able to request this. They will be sent a standardised letter including their scores on each measure and, where available, what this score is suggestive of (e.g. mild depression). Some of the measures do not have standardised cut-offs. This will only be sent if requested and not for all participants.

Any participant who scores in the severe range on the GAD-7 (scores of 15-21) or the PHQ-9 (scores of 20-27), or who scores 3 on question 9 of the PHQ-9 (this question relates to thoughts of harm to self) will have a letter sent to their GP advising them of this, and the participant will receive a copy.

Any disclosure made to the researchers that constitutes a safeguarding issue, or a potential risk to self or others, will be shared with the clinical team and managed appropriately as per the usual clinical care pathway, including contacting other agencies where indicated. Where participants report mental health problems such as anxiety or depression, based on the Clinical Psychologist's judgement, they will be signposted or, where appropriate, referred, to appropriate mental health services as is usual practice in their clinical care. This might include, for example: their local mental health trust's Single Point of Access; Improving Access to Psychological Therapies (IAPT); the London-wide Type 1 Disordered Eating Service.

If the participant raises concerns that they do not wish to be shared with their clinical care team, but the researcher feels should be shared, an anonymised discussion will be initiated with the Principal Investigator, and if appropriate, the clinical care team. The Trust Ethics Committee can also be consulted, if appropriate, to consider what is in the participant's best interests.

Participants' GPs will not be informed of their participation in the study as it will not affect their care.

End of study will be defined as last subject last visit (LSLV).

Sub-study – Qualitative semi-structured interview

Of the participants who are enrolled into the study (and who have consented to be contacted for an interview) the research team plan to select approximately 16 whose HAS scores are relatively higher than other participants in order to conduct a qualitative semi-structured interview. This will be judged from previous research and participants who score in the upper quartile of the entire measure. (Singh *et al.,* 2014). Participants of varying backgrounds will be selected to ensure a mix of demographics, diabetes duration, HbA1c etc. This is in order to ensure a heterogeneous pool of participants to inform our hypothesis.

Participants will not be reconsented to take part in the interview study as they will have already opted in on the original consent form, having read the PIS which details this sub study. The

interviews will take place either remotely via Microsoft teams or face to face at St Mary's hospital.

An inductive, exploratory approach will be taken to learn more about fear of hyperglycaemia. An initial semi-structured interview schedule will be used to guide the interviews and, in line with the grounded theory approach, the information gathered from interviews will be used to shape and inform subsequent participant interviews as hypotheses and theories are developed. The interview will be conducted by a clinical psychologist, will last a maximum of 90 minutes and will be recorded and then transcribed verbatim by the clinical psychologist.

The audio recording will be anonymous and will be destroyed once the interview has been transcribed. The interview will be transcribed in pseudonymous format. After the interview, the clinical psychologist will email the participant with the themes that they identified during the interview. This is called a credibility check and the participant will be asked to respond with confirmation that they agree/disagree with the themes that have been outlined. A third party (who will be an appropriately qualified member of the research team employed under ICHT) will review the pseudonymised transcripts and provide feedback. This is the second part of the credibility check. This third party will not have access to the identifiable codes.

The psychologist is experienced in sensitively discussing difficult and distressing topics with individuals and will routinely debrief all participants at the end of each interview. If during the course of interviews, individuals disclose actual or possible risk of harm to self or others, this will be assessed and managed using the same procedures that are used in a clinical setting.

7. STATISTICS AND DATA ANALYSIS

Approximately 350 participants have been identified. This includes people who attend the Imperial College Healthcare NHS Trust diabetes clinics, and people who have given the Imperial diabetes research team their consent to be contacted for research. Approximately 16 potential participants will be enrolled into the interview sub-study. This is based on the number estimated to be required to identify no new themes (i.e. reach saturation).

Of the participants who are enrolled into the study (and who have consented to be contacted for an interview) the research team plan to select approximately 16 whose HAS scores are relatively higher than other participants in order to conduct a qualitative semi-structured interview. This will be judged from previous research and participants who score in the upper quartile of the entire measure. (Singh *et al.,* 2014). Participants of varying backgrounds will be selected to ensure a mix of demographics, diabetes duration, HbA1c etc. This is in order to ensure a heterogeneous pool of participants to inform our hypothesis.

This study contains both descriptive and quantifiable data. The quantitative outcomes may be either ordinal or categorical, and proportions tests, including Chi squared tests, t-tests and ANOVAs will be used to determine differences between these outcomes.

The descriptive data will be tabulated and presented as such without statistical analysis. Interviews will be audio-recorded and transcribed verbatim. They will be analysed using a grounded theory approach (Corbin & Strauss, 1990), which aims to develop a set of concepts that provide a theoretical explanation of the phenomenon being studied. Analysis will take place alongside data collection, as it will inform and direct subsequent interviews. Credibility checks (Elliott, Fischer & Rennie, 1999; Stiles, 1993) will involve a third-party examining sections of analysed interview transcripts and providing feedback. In addition to this the researcher will contact the interview participant participants to check the themes with the interview participant and providing feedback.

All personal details will be sent via encrypted email (nhs.net).

Record linking participant information to study ID will be stored securely on an Imperial College NHS trust Computer. All study data will be stored in a pseudonymised format in an encrypted database on an Imperial College NHS trust computer OR Imperial College London computer.

Audio recordings will be recorded on a secure dictaphone in pseudonymised form and once transcribed will be destroyed. All transcribed data will be stored on an ICHT or ICL computer in pseudonymous form.

Direct quotations may be published in anonymous fashion. The NHS Code of Confidentiality will be followed at all times. All data is to be stored in a pseudonymised form by using study codes for de-identification of participants. Examples of such a code includes: HYPE001 (assigned in order of enrolment). Identifiable Personal data will be kept in files in a locked office within Imperial College London, accessible only by the research/clinical team. Pseudonymised data will be stored in a password encrypted spreadsheet on ICHT/ICL computers, accessible only by the research team.

Data and all appropriate documentation will be pseudonymised and stored for a minimum of 10 years after the completion of the study in line with Imperial College policy.

8. REGULATORY ISSUES

8.1 Ethics approval

The Study Coordination Centre has obtained approval from the Cornwall and Plymouth Research Ethics Committee (REC) and Health Regulator Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before accepting participants into the study or any research activity is carried out. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2 Consent

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered, and time allowed for consideration. Signed participant consent should be obtained. The right of the participant to refuse to participate without giving reasons must be respected. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant's best interest, but the reasons for doing so should be recorded. In these cases, the participants remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

8.3 Confidentiality

Anonymised quotes may be used in publications if the participant has given written informed consent. The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

8.4 Indemnity

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study.

8.5 Sponsor

Imperial College London will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

8.6 Funding

The study is funded by the Imperial Health Charity. No payments will be made to participants or investigators in this study.

8.7 Audits

The study may be subject to inspection and audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research.

9. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through Prof Nick Oliver.

10. PUBLICATION POLICY

The study will be registered on the clinicaltrials.gov system and results will be disseminated by peer reviewed scientific journals, internal report, conference presentation and publication on websites. No identifiable personal data will be published. Anonymised quotes may be included in publications if the participant has given informed written consent. All anthropometry and personal clinical data will be expressed as mean/ median and spread of the population in the study. All participants will be informed of the results by letter at the conclusion of the study and details of any publications that arise from the study will be disseminated to participants.

11. REFERENCES

1. JDRF (2019). Type 1 Diabetes facts and figures. https://jdrf.org.uk/information-support/about-type-1- diabetes/facts-and-figures/ (Accessed 03.12.2019)
2. Strandberg RB, Graue M, Wentzel-Larsen T et al. (2014). Relationships of diabetes-specific emotional distress, depression, anxiety and overall well-being with HbA1c in adult persons with type 1 diabetes. Journal of Psychosomatic Research, 77, 174-179
3. Todd PJ, Edwards F, Spratling L et al. (2017). Evaluating the relationships of hypoglycaemia and HbA1c with screening-detected diabetes distress in type 1 diabetes. Endocrinology, Diabetes and Metabolism, e00003. 10.1002/edm2.3.
4. All Parliamentary Group for Diabetes (2018). Diabetes and Mental Health Report (Available at: https://diabetesappg.files.wordpress.com/2018/08/appg-mental-health-report_v3.pdf)
5. Choudhary P, Amiel SA. (2018). Hypoglycaemia in type 1 diabetes: technological treatments, their limitations and the place of psychology. Diabetologia, 61, 761-769
6. McKechnie, V, Reddy M, Oliver N. (2019). Impact of clinical psychology interventions in diabetes. Diabetic Medicine, 36, suppl.1, 151.
7. Anderbro T, Gonder-Frederick L, Bolinder J et al. (2014). Fear of hypoglycaemia: Relationship to hypoglycemic risk and psychological factors. Acta Diabetologica, 52(3)
8. Leiter LA, Yale JF, Chiasson JL et al. (2005). Assessment of the impact of fear of hypoglycemic episodes on glycemic and hypoglycaemia management. Canadian Journal of Diabetes, 29, 3.
9. Cox DJ, Irvine A, Gonder-Frederick L et al. (1987). Fear of hypoglycaemia: Quantification, validation and utilization. Diabetes Care, 10, 5, 617-621
10. Gonder-Frederick LA, Schmidt KM, Vajda, KA et al. (2011). Psychometric properties of the hypoglycaemia fear survey-II for adults with type 1 diabetes. Diabetes Care, 34, 4, 801-806
11. National Institute for Health and Care Excellence (2016). Type 1 diabetes in adults: diagnosis and management (NG17).
12. Singh H, Gonder-Frederick L, Schmidt, K et al. (2014). Assessing hyperglycaemia avoidance in people with Type 1 diabetes. Diabetes Management, 4(3), 263-271.
13. McDonald B, Macmaster B, Ramli R, Oliver N, Reddy M. (2020). Management of

hypoglycaemia in the emergency department in a large London hospital trust. Diabetes UK Professionals Conference, Glasgow, UK.

14. Corbin J, Strauss A. (1990). Grounded theory research: Procedures, canons, and evaluative criteria. Qualitative Sociology, 13, 1.
15. Elliott R, Fischer CT, Rennie DL. (1999). Evolving guidelines for publication of qualitative research studies in psychology and related fields. Br J Clin Psychol, 38(3),215–29
16. Stiles WB. (1993). Quality control in qualitative research. Clinical Psychology Review, 13(6), 593-618.

12. APPENDICES

Appendix 1. Study Questionnaires (attached separately)

- Hyperglycaemia avoidance scale (HAS)
- Hypoglycaemia fear survey (HFS-II)
- Problem areas in diabetes scale 5 (PAID-5)
- Patient health questionnaire (PHQ-9)
- Generalised anxiety disorder scale (GAD-7)
- State trait anxiety inventory (Trait subscale)
- semi-structured interview

Appendix 2. Data Flow Mapping