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Evaluation of integrated diabetes and mental health services to support patients with Type 1 diabetes-related disordered eating

Research team contacts

Prof Peter Bower NIHR Rapid Service Evaluation Team (REVAL) Centre for Primary Care & Health Services Research School of Health Sciences University of Manchester peter.bower@manchester.ac.uk	Elaine Harkness NIHR Rapid Service Evaluation Team (REVAL) Centre for Primary Care & Health Services Research School of Health Sciences University of Manchester elaine.f.harkness@manchester.ac.uk
Paul Wilson Co-Director NIHR Rapid Service Evaluation Team (REVAL) Centre for Primary Care & Health Services Research School of Health Sciences University of Manchester paul.wilson@manchester.ac.uk	Jo Dumville Co-Director NIHR Rapid Service Evaluation Team (REVAL) Division of Nursing, Midwifery & Social Work School of Health Sciences University of Manchester jo.dumville@manchester.ac.uk
Stephanie Gillibrand NIHR Rapid Service Evaluation Team (REVAL) Centre for Primary Care & Health Services Research School of Health Sciences University of Manchester stephanie.gillibrand@manchester.ac.uk	Maartje Kletter NIHR Rapid Service Evaluation Team (REVAL) Division of Nursing, Midwifery & Social Work School of Health Sciences University of Manchester maartje.kletter@manchester.ac.uk
Cristianne Bukhari Programme Manager NIHR Rapid Service Evaluation Team (REVAL) Division of Nursing, Midwifery & Social Work School of Health Sciences University of Manchester cristianne.bukhari@manchester.ac.uk	

Evaluation Protocol Summary

Title	Rapid evaluation of integrated diabetes and mental health services to support patients with Type 1 diabetes-related disordered eating
Background	In response to growing recognition of unmet need, NHS England commissioned a pilot of two, exploratory, Type 1 diabetes-related disordered eating services. The pilot implementation and evaluation were conducted during the COVID-19 pandemic, and this, combined with the relatively small amount of participant data available, limited conclusions that could be drawn. NHS England is now providing two years of national funding to support Type 1 diabetes-related disordered eating services to be established in London, Midlands, East of England, North West, North East and North Cumbria, Yorkshire and Humber regions. The aim is to support greater understanding of how these services can be delivered and to conduct an evaluation to support future, local commissioning decisions, such that the decisions, on whether to locally fund the services, can be taken at the end of the two-year national funding period.
Aims	The overarching aim of this evaluation is to explore how Type 1 diabetes-related disordered eating services are being implemented in the eight geographical settings. We will: 1. Describe service delivery models and how they were developed and are evolving. 2. Investigate whether service implementation is being achieved (compared against service specifications) and in a way that is acceptable to staff. We will explore contextual factors that contribute to implementation progress. 3. Investigate how service delivery is being sustained, exploring any adaptations made to services over time, with the aim of supporting on-going activity and enhancing service delivery. 4. Investigate the experiences of service users. 5. Explore the costs of the service against the clinical consequences for service users.
Design	Multi-site, multi-methodologies study. Interviews with staff, wider stakeholders and service users who are either delivering or in receipt of the Type 1 diabetes-related disordered eating services. A cost -consequences analysis.
Sample	The evaluation will cover all eight sites (which includes the original pilot sites – one original pilot site is now split into two).
Timelines	Sense-making and mapping of case sites: June 2023 to July 2023 Staff interviews and surveys (including cost data collection), service user interviews, analysis and synthesis: August 2023 to January 2024 Production of cost consequences analyses: February 2024 Final stakeholder workshop, final synthesis and report writing: February to April 2024
Funding	This research is an independent evaluation undertaken by the NIHR Rapid Service Evaluation Team (REVAL). REVAL is funded via a competitive review process by the NIHR Health and Social Care Delivery Research (HSDR) Programme (NIHR151666). The views expressed in this protocol are those of the author(s) and not necessarily those of the NIHR, NHS England or the Department of Health and Social Care.

Introduction

Approximately 400,000 people in the UK are estimated to have Type 1 diabetes at any one time; around 10% of these people are aged 20 years or less (Gregory 2022). Type 1 diabetes commonly manifests during adolescence with incidence peaks in early childhood and at puberty. A Type 1 diabetes diagnosis means initiation of insulin therapy and modification of eating habits to optimise healthy glycaemic control.

Adolescence is also the most common period for the onset of eating disorders, although these can manifest throughout the life course. Global Burden of Disease study estimates suggest that in 2019, globally, 700 people per 100,000 suffered from an eating disorder (95% CI 492 to 965 per 100,000); an increase of almost 15% from 1990 (Castelpietra et al 2022). A systematic review and meta-analysis of 94 epidemiological studies estimates that lifetime prevalence of an eating disorder is 8.4% (95% CI 3.3 to 18.6%) for women and 2.2% (95% CI 0.8 to 6.5%) for men (Galmiche et al 2019).

People with Type 1 diabetes may be at increased risk of disordered eating. The increased focus on eating patterns and food intake required by people with Type 1 diabetes, alongside the need for daily insulin and negative experiences from their diagnosis, can impact on eating practices and related behaviours. Over 20 years ago, a cross sectional survey found adolescent females in Canada had 2.4 the odds of a diagnosed eating disorder compared with matched non-diabetic controls (n = 356 participants with diabetes and 1098 controls) (Jones et al 2000). More recently a study from the Danish Registry for Diabetes in Childhood and Adolescence (506 adolescents with Type 1 diabetes; mean age 14.7 years; mean HbAC1 5.2%) reported that 34% of participants were considered to have one or more indicator of overeating, sub-clinical binge eating or clinical binge eating (Marks et al 2021).

Insulin restriction or omission to promote weight loss is also a recognised issue in people with Type 1 diabetes and disordered eating: this is sometimes called diabulima (Coleman and Caswell 2020). Induction of hyperglycaemia though poor glycaemic control means glucose is excreted rather than absorbed, which can lead to weight loss but also serious health problems. These include increased risk of elevated blood sugars (measured HbA1c), diabetes ketoacidosis and premature onset of complications of diabetes such as retinopathy and nephropathy. Previous systematic reviews have shown a lack of evidence-based approaches to support people with Type 1 diabetes and disordered eating (Clery et al 2017).

In response to growing recognition of unmet need in this complex patient group, NHS England commissioned a pilot of two exploratory Type 1 diabetes-related disordered eating services. An evaluation of these pilots reported data on 69 service users who were accepted onto the pathway (site 1 n = 23 and site 2 n = 46). The pilot implementation and evaluation were conducted during the COVID-19 pandemic, and this, combined with the relatively small amount of service use data available, limited conclusions that could be drawn. The evaluation reports that patients and staff were generally supportive of the services delivered.

NHS England is now providing 2 years of national funding to support further Type 1 diabetes-related disordered eating services to be established in the Midlands, East of England, North West, North East and Yorkshire regions. This evaluation aims to explore the early implementation (new sites) and on-going implementation (existing sites) of these services. The evaluation will provide insights to support greater understanding of, if and how, these services can be delivered in a real-world setting and support future local commissioning decisions, such that the decisions on whether to locally fund the services can be taken at the end of the national funding period. The exploratory Type 1 diabetes-related disordered eating services will cover a total of eight sites (including an initial pilot site that is now split into two).

Here we describe the planned evaluation of services delivered across these eight sites over the next two years. These eight sites include five that have been funded recently to start a Type 1 diabetes-related disordered eating service and three existing (previous pilot sites) with existing Type 1 diabetes-related disordered eating services.

Proposed evaluation

We suggest a phased evaluation that will ultimately produce a single final report but allow interim findings to be delivered during the evaluation. We suggest this approach as it will maximise timely insights and learning opportunities.

Draft overarching evaluation aim

The overarching aim of this evaluation is to explore how Type 1 diabetes-related disordered eating services are being implemented in eight current UK sites.

We aim to:

(1) Describe service delivery models and how they were developed and are evolving. (workstream 1)

(2) Investigate whether service implementation is being achieved (compared against service specifications) and in a way that is acceptable to staff. We will explore contextual factors that contribute to implementation progress. (workstream 2).

(3) Investigate how service delivery is being sustained, exploring any adaptations made to services over time with the aim of supporting on-going activity and enhancing service delivery (workstream 2 below).

(4) Investigate the experiences of service users (workstream 3)

(5) Explore the costs of the service against the clinical consequences for service users (workstream 4).

These aims will be achieved by aiming to address the following specific research questions.

Workstream 1: Mapping current Type 1 diabetes-related disordered eating models to explore implementation:

1. *How are Type 1 diabetes-related disordered eating services configured in each site (both new and existing): what are the core services offered, who are they aimed at, how do people access the service, and is service utilisation time-limited? We will also explore the catchment area for referrals to the service and the pathways to referral.*
2. *For existing sites, has service configuration changed over time, and if so, how?*

3. *Were there any existing shared care or exploratory Type 1 diabetes-related disordered eating services between mental health, diabetes and allied health services at sites before the pilot?*
4. *What are similarities and differences in Type 1 diabetes-related disordered eating services being used (e.g., in terms of leadership and wider workforce, setting, previous context and access pathways)?*
5. *What is the extent of service integration in these models and how does it connect to other services, including primary care?*
6. *What are the expected patient numbers and outcomes for Type 1 diabetes-related disordered eating services from the perspective of staff?*
7. *What are local commissioning contexts, in terms of where services sit in health and care systems, and who will be responsible for commissioning and recommissioning decisions?*
8. *How will local commissioners judge the success and long-term need and feasibility of Type 1 diabetes-related disordered eating services?*

Workstream 2: Staff insights into the delivery and impact of early and on-going implementation of Type 1 diabetes-related disordered eating services

9. *Are Type 1 diabetes-related disordered eating service models coherent, implementable and acceptable to staff?*
10. *What are staff members' experiences of training for and delivering care within the Type 1 diabetes-related disordered eating service models?*
11. *Do teams think Type 1 diabetes-related disordered eating service models are working well? What aspects are considered less successful?*
12. *What are the barriers and facilitators to the implementation of the Type 1 diabetes-related disordered eating service models from a staff perspective?*
13. *What are staff experiences of treating this patient group and how does the service model impact on these experiences?*
14. *In terms of setting a national standard of care, do elements in the NHS England-specified service pathway need to be added, changed or removed?*

Workstream 3: Service user insights into receipt of Type 1 diabetes-related disordered eating services

15. *What are service user views on the acceptability of the Type 1 diabetes-related disordered eating service models and their experience of receiving care?*

Workstream 4: Insights into clinical and cost impacts of service delivery

16. *What are the impacts of the Type 1 diabetes-related disordered eating services on costs and activity of health care and patient outcomes?*

Evaluation structure and use of theoretical frameworks

We will use the Health Disparities Framework (Kilbourne et al 2006) as the overarching framework for this evaluation. This framework recognises that the determinants of health inequalities are multi-level and that any evaluation seeking to understand these must focus

not only on the individual recipients of care, but on the clinical encounters, the providers involved in delivery and the ways by which services are shaped by the health system in which they are delivered. We will use this framework to structure our understanding of how each delivery model is developed and implemented, and to assess whether they represent an efficient way to organise and deliver care for this complex patient population.

As micro, meso and macro contextual factors will influence local implementation, we will use the Consolidated Framework for Implementation Research (CFIR) for understanding implementation. CFIR (Damschroder 2009, 2022) is widely used in implementation research and comprises a comprehensive taxonomy of factors likely to influence implementation.

Implementation of new services can also be understood as a critical event in a system that displaces existing practices and leads to the evolution of new processes and ways of working. Therefore, we will also draw on Normalisation Process Theory (NPT) to explore factors that support embedding of new practices into normal care, and factors that can inhibit such adoption (May 2009). NPT and CFIR are complementary – CFIR describes contextual determinants of change and NPT helps us to understand the mechanisms through which new ways of working become part of routine practice (Schroeder 2022).

Integration with NHS England's quantitative analyses

Our evaluation will dovetail with NHS England's analyses of quantitative data that will explore the impact of services on clinical outcomes. Workstreams 1 to 3 of the proposed REVAL evaluation of early implementation are a process evaluation, designed to complement NHS England's quantitative work. Additionally, in workstream 4, we will present service resource use and associated cost data alongside interim changes in health outcomes to give insights into care costs versus the health consequences.

For information here we detail the items being collected in NHS England's minimum data set (MDS) (Table 1).

Whilst our team are not directly involved in the analyses of clinical data we are proposing a *clinical data analyses group* is convened including members of the REVAL and NHS England team. In this way we can maintain links with this element of the work, offering advice as required. This also ensures on-going insights into the data relevant for the proposed cost-consequences work (Workstream 4).

Table 1: Summary of information collected in the proposed minimum dataset

	Timepoint (months)						
	0 (baseline)	6	12	18	24	At discharge	On-going/at point of analyses
Gender	□	n/a	n/a	n/a	n/a	n/a	n/a
Ethnicity	□	n/a	n/a	n/a	n/a	n/a	n/a
BMI	□	n/a	n/a	n/a	n/a	n/a	n/a
Year of diabetes onset	□	n/a	n/a	n/a	n/a	n/a	n/a
Service entry/exit	□	n/a	n/a	n/a	n/a	□	n/a
Reason for discharge	n/a	n/a	n/a	n/a	n/a	□	n/a
HbA1c	□	□	□	□	□	□	n/a
DDS-2	□	□	□	□	□	□	n/a
DEPS-R	□	□	□	□	□	□	n/a
GAD7	□	□	□	□	□	□	n/a
PHQ9	□	□	□	□	□	□	n/a
EQ-5D	□	□	□	□	□	□	n/a
WSAS	□	□	□	□	□	□	n/a
Secondary Care Mental Health Admissions	□	n/a	n/a	n/a	n/a	n/a	□
Hospital episode for Diabetic ketoacidosis (DKA) and other diabetes-related episodes	n/a	n/a	n/a	n/a	n/a	n/a	□

Workstream 1: mapping current Type 1 diabetes-related disordered eating service models to explore implementation

Timeframe: June-July 23

Mapping of Type 1 diabetes-related disordered eating service models

We will meet with lead contacts for each service to explore key contextual factors surrounding implementation of the Type 1 diabetes-related disordered eating services. These informal 'mapping' consultations will be used, in addition to documentation provided by NHSE, to record additional information on the components of each service. Mapping conversations will give a clearer overview of how services have been developed, designed, implemented and targeted to specific population groups. We will use the TIDieR framework to capture data (Hoffman 2014).

We will ask to record the discussions, which will be via Teams, Zoom or the phone, but if individuals would prefer to talk without a recording this is also possible. If an individual is uncomfortable with the recording process at any time during the discussion we will stop the recording. All audio files will be deleted after our note taking process is complete.

We will also speak to local commissioners in each of the pilot sites. We will explore the information, insights and data that commissioners want when making future commissioning

decisions. This will allow us to map evaluation deliverables to end user evidence needs. Our current mapping of issues raised in the evaluation brief (supplied by the policy team overseeing this pilot work) to the proposed evaluative work accompanying the pilot is detailed in Appendix 1. This will be amended iteratively as required and in conjunction with all relevant stakeholders.

Phase 1 Deliverables

- Describe pathway structure and functions in each site.
- Describe variation in Type 1 diabetes-related disordered eating service models across sites.
- Outline the mechanisms of integration between different clinical services.
- Insights into the activity and outcomes anticipated by each model.
- Insights into commissioner evidence requirements to support future decision making.

Workstream 2: Staff insights into the delivery and impact of early and on-going implementation of Type 1 diabetes-related disordered eating services

Timeframes: Sep 2023 to Mar 2024

Approvals – to be obtained by REVAL team

Case study set-up

A REVAL team member will be allocated to each site to build relations with key contacts. A site initiation meeting will be set up with the key Type I diabetes-related disordered eating service lead contact to explain the anticipated activities and manage expectations about what will be involved and agree appropriate communication. This meeting will likely build on from previous mapping conversations in workstream 1 and offer an opportunity for the REVAL team to gather further information on activities and progress.

We will also discuss the availability of relevant documentation, to enhance our understanding of local service design, development and current activities.

Staff interviews (Sep 2023 – Dec 2023)

We will aim to interview samples of stakeholders at each site. Through purposive snowball sampling, we will start with designated contacts at each site and seek to sample interviewees including: mental health and diabetes clinical and managerial leads, as well as allied health professionals e.g., dietitians. Interviews will cover CFIR-informed topics including activities the individual is responsible for delivering and how this relates to the service more broadly; the current progress of the programme and personal experiences of it; views of local context; perceived readiness for implementation locally; barriers and facilitators linked to areas discussed; experiences of multi-disciplinary team working in the context of the Type 1 diabetes-related disordered eating service; insights into perceived successes and impacts and anticipated future changes. We will also explore the role of leadership in the implementation process.

To recruit staff participants, information sheets will be emailed to relevant staff and partner organisations will be drawn on to disseminate information about the evaluation where appropriate. The interviews are likely to be conducted remotely. Once consent has been

provided, each interview will be guided by a topic guide. Broadly, areas covered will be informed by role and the underpinning frameworks and theories guiding the work including those shaping the exploration of implementation (CFIR and NPT).

Staff surveys (Sep 2023, Mar 2024)

We are also keen to explore wider staff views and perceptions of the Type 1 diabetes-related disordered eating service model*s* and propose an on-line, anonymous survey aimed at all team members, to be used at the start and later in the service implementation to assess changes in staff perspectives. The survey would include the validated and widely used Normalisation MeAsure Development questionnaire (NoMAD), which is designed to measure constructs of NPT. We will also use the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure. These measures show good psychometric properties and are brief (12 items in total across the three measures) and easy to administer (Weiner et al 2017).

Data analysis

We will adopt a rapid approach to the analysis that is consistent across the case study sites. Interviews will be audio-recorded with consent, transcribed and thematically analysed using a modified framework approach (Gale 2013). This will involve:

- creating a summary template based on the topic guide, with space provided for other observations, unexpected findings and key quotations
- completing the summary template following each interview, using field notes from the interviewer; discussing the analysis as a research team
- iterative refinement of the template as the data collection progresses
- transferring the summary templates to a matrix

The matrix of summarised data provides a structure for analysis and interpretation which is useful for policy research (Gale 2013). The coding framework will be iteratively developed as the interviews continue, through discussion at regular analysis meetings and through discussions with NHS England and members of a planned advisory group. Surveys will be analysed using relevant scoring procedures and presented descriptively.

Workstream 2 deliverables

- Insights into local progress and potential challenges and successes noted;
- Insights into fidelity against the planned Type 1 diabetes-related disordered eating service;
- Understanding of specific barriers and facilitators to implementation;
- Understanding of staff experiences, what is working well and what is less successful;
- Insights into impacts on staff relationships and other service interfaces

Workstream 3: Service user insights into receipt of Type 1 diabetes-related disordered eating services

Timeframes: Oct 2023 to Jan 2024

Approvals to be obtained by REVAL team

We will carry out interviews with service users of Type 1 diabetes-related disordered eating services in each case study site. These interviews will focus on capturing the acceptability of Type 1 diabetes-related disordered eating service models and people's experience of receiving this care. We aim to recruit a maximum of 40 service users, which would represent approximately four users from each of the sites. Discussions with a charity representing service users has indicated that focus groups may also be a useful data collection approach to gain informative insights with services. We plan to start with interviews and explore the potential value of focus groups as we proceed. We will also explore service user views of focus groups with our Advisory Panel.

Participant recruitment

Details of the study will be provided to users of the Type 1 diabetes-related disordered eating services by members of the clinical team. We will use a purposive sampling approach that is considered for each team and informed by information from workstreams 1 and 2. Our approach will ensure we access a range of local representation and experience and we will endeavour to use innovative approaches to facilitate recruitment amongst under-served groups as highlighted in CORE20PLUS5 the NHS England strategy which aims to reduce healthcare inequalities in targeted populations (https://www.england.nhs.uk/about/equality/equality-hub/national-healthcare-inequalities-improvement-programme/core20plus5/). Factors considered for sampling will include duration of diabetes and eating disorder, gender, age, socio-economic status and ethnic minority background.

The interviews or focus groups themselves are likely to be conducted remotely but where necessary we will facilitate face-to-face interviews. Each service user interview or focus group will be guided by a specific topic guide that will cover topics relevant to the research questions. This will include awareness and knowledge of the service; experience of the local service including both positive and negative experiences; perceptions of advantages and disadvantages of the service. We will also consider how service user views captured in each site may be incorporated into service developments/refinement. This is to consider the value of a patient reported experience measure, which is not currently included in the minimum data set (MDS).

Data analyses

As with the staff interviews, we will use a modified framework approach (Gale 2013) for analysis of service user data with comparison between case study sites. The developed analytical framework in workstream 2 (staff interviews) will be used to analyse data collected in workstream 3. If new themes emerge these will be added to the developed framework.

To gain a thorough understanding of experiences and insights from the multiple perspectives of those involved in delivering and accessing Type 1 diabetes-related disordered eating services, we will triangulate data collected from service user participants with the data collected from staff members with the help of the framework matrix as applied in Workstream 2.

Workstream 3 Deliverables

- Insights into service user awareness of Type 1 diabetes-related disordered eating services and their experiences of accessing these**;**

- Service user experiences of Type 1 diabetes-related disordered eating service models;
- Service user perceptions on how Type 1 diabetes-related disordered eating service models have impacted on their care and outcomes;
- Gain insights of important future outcome measures for the service;
- Insights into any unintended consequences of local implementation.

Workstream 4: Cost-consequences analyses of early Type 1 diabetes-related disordered eating services

Timeframes: Sep 2023 to Feb 2024

Approvals – NHSE will obtain required IG for MDS data analyses

An economic analysis is required, which the REVAL team will undertake using anonymised individual clinical data supplied by the NHS England analyst from the MDS. We have considered several factors in deciding on the most suitable approach and will undertake a cost-consequences analyses.

Cost-consequence analysis involves clear presentation of how the services impact on various measures (which could include activity and cost implications alongside a range of outcomes) – but without formal integration of these data. That is no single measure is generated unlike the output of a cost-effectiveness analysis (e.g., a cost-per-QALY measure).

The advantage of a cost-consequence study is that it supports decision makers to make subjective, yet informed, judgements about the relevance of the various consequences to the context of their specific decision. The data can also be used in future evaluations as required.

We acknowledge that this approach is limited by the lack of comparator group, which imposes a bias that may under- or over-estimate impacts on the consequence measures. However, addressing these issues would require identification of patients eligible but not in receipt of the service and the collection of an identical dataset in this group: this approach is not possible currently.

The approach is also limited, necessarily, by the limited time of follow-up. Follow-up time should capture all implications. Modelling approaches could address this issue: estimating the consequences over a sustained time-period. Such modelling will be beyond the timescale and resources available for this rapid evaluation.

Justification of the cost-consequences approach

Because of the timescales of this rapid evaluation, we are suggesting an intermediate cost consequences analyses with costs collected related to the delivery of the early implementation of the integrated service only and outcomes taken from the MDS data e.g., changes in EQ-5D and other clinical measures. This approach is limited by the timeframe of follow-up and would not capture impacts on health care service use (and costs) impacted beyond the delivery of the service.

Over time, as data accrues, outcomes related to additional use of health care resources such as in-patient stays will become more relevant. We will consider how to support further cost-consequence, or additional health economic analyses, as the pilot continues to accrue data.

Collection and costing of health care resources: Staff cost and associated costs of Type 1 diabetes-related eating disorder services

Staff inputs will be collected from individual sites, reflecting the service model being provided. These data will be collected through discussion with lead staff at each site and supported with a survey to gather information if this is required.

Estimates of additional staff time for setting up the service in the first year will also be collected. The staff role and where possible an agenda for change grade will be gathered and expressed in terms of whole-time equivalents for each staff category. Costs will be applied to these resources using the most recent Personal Social Services Research Unit (PSSRU) Cost of Health and Social Care publication and uplifted to current prices.

Collection and costing of health care resources: Consequences assessed as part of this rapid evaluation

We will also assess the use of health care resources associated specifically with the Type 1 diabetes-related disordered eating service. For example, where patients receive a glucose monitoring device that they would not otherwise have access to this resource use will be noted and costed.

We will not measure capital costs.

Outcome data, presentation and interpretation

Because of the timing of the evaluation our initial focus will be on the presentation of clinical data collected during the early implementation of the service via the MDS. We will present change data for all measures collected as part of the MDS that are available at the time of reporting, which will be the longest period possible within the timescales of the evaluation and to fit with NHS England analytical plans. Change will be calculated from baseline (Table 2). We are not expecting to have individual patient data that pre-dates the baseline in the MDS, however, if this were obtained, we would explore maximal use of these additional data in the analyses. Change values will be presented with 95% confidence intervals to reflect the precision of estimates, which will be impacted by sample sizes – but the volume of available data is out with the control of the evaluation team.

Table 2: Anticipated consequence measures included in cost-consequences analyses

Consequence	*Baseline*	*Follow-up*	*Change*
HbA1c			
DDS-2			
DEPS-R			
GAD7			
PHQ9			
EQ-5D			
WSAS			

Workstream 4 Deliverables

- A summary of the costs of Type 1 diabetes-related disordered eating services including staff and relevant non-staff costs
- A summary of change data from the MDS at the point of analyses to allow early consideration of cost-consequences of the service.

PPIE

As a team we have committed to ensure that we actively listen to and involve citizens in all aspects of our work. A public, patient involvement and engagement plan for the evaluation has been developed in partnership with our REVAL public contributors.

The research team is in the process of forming a Public Advisory Panel. Members bring a range of skills, knowledge, and expertise and will ensure that a diverse public voice informs the evaluation that we do and the methods we use. The Advisory Panel model will be iteratively formed reflecting the nature of the evaluation (i.e. Workstreams, 1, 2, 3 & 4), where we will re-visit our Advisory Panel model throughout the course of the evaluation to include additional representation and expertise as necessary. We will consult with the Advisory Panel at regular points during the evaluation lifespan to facilitate ongoing collaboration for input and feedback into the evaluation process, including in the early stages of the evaluation seeking advice on recruitment approaches, and development of interview topic guides.

Research Team

Peter Bower	Lead
Elaine Harkness	Data Analysis
Jo Dumville	Evaluation support
Paul Wilson	Implementation Science support
Maartje Kletter	Research Associate
Will Whittaker	Health Economics
Saima Arif	Health Economics

Proposed advisory panel

We will have a project advisory panel for this work. We have made approaches to NHS-England and JDRF for suggested healthcare professionals we can approach who are also independent from the sites setting up the Type 1 diabetes-related disordered eating service models that are being evaluated. We have identified one healthcare professional who we will speak to about joining our advisory panel.

We have also made an approach to the charity BEAT (Beat Eating Disorders) and discussed our research with their Co-production and Participation Co-ordinator, with the view to exploring the potential for an integrated approach to involving service users. We have had an initial meeting with the Applied Research Collaborative (ARC) young persons advisory group and have identified four individuals with lived experience of Type 1 diabetes-related disordered eating via JDRF (Juvenile Diabetes Research Foundation) who are keen to be involved in our advisory panel to ensure service user involvement and engagement with the project (Table 3).

Table 3: Proposed Advisory Panel

Health care professionals	**Contacts via JDRF** **Diabetes UK**
Service users and public voice	**BEAT (Beating Eating Disorders)** **Diabetes UK** **Juvenile Diabetes Research Foundation (JDRF)** **ARC Greater Manchester Young Persons' Advisory Group**

Other regular stakeholder meetings

Regular meetings with the NHS England project team and liason with the Type 1 diabetes-related disordered eating Expert Reference Group, chaired by **Jonathan Valabhji, National Clinical Director for Diabetes and Obesity, NHS England**

Lucy Holmes	**Strategy Lead, National Diabetes Programme, NHS England**
Charlotte Keegan	**Project Delivery Manager, National Diabetes Programme, NHS England**
Fiona Earnshaw	**Senior Analytical Manager, Diabetes Programme, NHS England**

Dissemination and knowledge mobilisation

We aim to maximally disseminate and mobilise our evaluation findings to meet national and regional decision-making need. We will actively engage with key stakeholders at all stages of the research process, not only to ensure efficient use of NIHR resources, but also to maximise the impact and use of findings as they emerge. This active engagement is facilitated, but the co-production model used through-out the evaluation.

We will meet regularly with members of the NHS England National Diabetes Programme team, ensuring we build this relationship and use the network to provide timely feedback through-out the evaluation. As well as the team itself we will liaise with the Expert Reference Group that is advising the NHS England team on this service delivery innovation. Through representation on this Expert Reference Group, we are also developing links with third sector organisations, including Diabetes UK. Through this network we will seek opportunities to share early insights with relevant wider, professional, policy and commissioning teams as the work progresses. Also via these links our work will be cascaded, as required, to the current parliamentary review on type 1 diabetes and disordered eating services, being led by Sir George Howarth MP and Rt. Hon Theresa May MP, with the charity Juvenile Diabetes Research Foundation (JDRF) acting as the secretariat for this review.

The work is of interest to service users and those who may be eligible to access this type of service were it available in their area. We are in discussions with the charity BEAT, which supports people with disordered eating including a focus on Type 1 diabetes and disordered eating. Through continued working, were appropriate and agreed, we aim to develop and disseminate lay-friendly information about the evaluation and its findings.

Ethical considerations

The main ethical considerations for the evaluation are recruitment, informed consent; confidentiality, anonymity and data protection:

Recruitment

The contact details of staff involved in the delivery of the Type 1 diabetes-related disordered eating services will be provided by NHS England. Potential participants will then be approached initially by an e-mail invitation from the evaluation team that will include a copy of the participant information sheet and consent form. Those indicating interest in participation will then be contacted and interviews will be arranged at a time to suit the participant – verbal consent will be recorded at this point (see below).

For the staff survey, potential participants will be identified by the local Type 1 diabetes-related disordered eating services. This will include those individuals who work for the Type 1 diabetes-related disordered eating service or have a related role in service delivery. We will ask the lead contact at each service to facilitate an email invitation from the evaluation team that will include a brief description of the study and a web link for the online survey. The online survey will contain a tick box at the beginning of the survey to indicate their consent. The survey will be anonymous, and responses will be submitted directly to the evaluation team once completed (IP address will not be collected).

For service users, potential participants will be identified by the Type 1 diabetes-related disordered eating services. The local teams will screen for those eligible to take part in service user interviews or focus groups. Eligible service users will be approached via the local teams, who will pass on information about the study through an invitation letter and ask patients to complete a consent-to-contact form. Once the consent-to-contact form has been completed and returned, the research team will make contact with the service user and participants will be given an Easy-Read Participant Information Sheet.

Informed consent

All potential research respondents who are recruited for interviews or focus groups will receive verbal and written information (participant information sheet) regarding the study and will be encouraged to ask questions prior to taking part. It will be made clear that participation is purely voluntary and respondents are able to withdraw from the study at any time, without giving a reason. We will obtain verbal consent before undertaking the telephone or Teams/Zoom interview or focus group, which we will audio-record separately to the interview or focus group audio-recording.

Participants in the staff survey will receive written information regarding the study in the invitation email and will be required to tick a box on the online survey to indicate their consent to take part in the study.

Confidentiality, anonymity and data protection

With consent, all interviews or focus groups will be audio-recorded using a secure University provided encrypted audio device. We will follow the University of Manchester's standard operating procedure for taking recordings of participants for research purposes: (http://documents.manchester.ac.uk/display.aspx?DocID=38446). Recordings of the consent

process and interviews or focus groups will be transferred from the device as soon as possible to secure University servers (so that de-identified data is stored separately to consent data) and then deleted from the device. Transcription of audio-recordings will be undertaken by a University of Manchester approved external transcription company. Audio recordings will be uploaded to the transcription company via a secure server. We will remove any personal identifying information (such as names, places) from transcriptions once they are returned. We will securely destroy the audio-recording of each interview or focus group, once an interview or focus group has been transcribed and the research team has checked the transcription for accuracy.

Once a respondent enters the study, they will be provided with a unique identifier. This means that data including field notes, audio recordings, transcriptions and demographic data will be identified only by their unique identifier and not the name of the respondent. Where necessary, we may also generalise job titles to protect the anonymity of those in specialist roles or where job titles are specific to an individual organisation. The 'pseudonymisation key' to the unique identifier and respondent's details (name, contact details, site and job title), will only be accessible to members of the research team and stored electronically on a University of Manchester secure server, separate to the de-identified data. Electronic data (such as digital audio-recordings, transcriptions, field notes, and demographic data) will be stored on a University of Manchester secure server. Hard copies of consent forms and demographic data will be kept in a locked cabinet in a locked room on University premises. Once the study is finished, data will be archived securely for 10 years, after which time it will be securely destroyed.

We are aware of the sensitive nature of this research for individuals. The research team has experience in conducting research on similar sensitive topics. We will maintain the anonymity of the participating organisations and individuals and will publish findings that are anonymised and aggregated. Individual participants are assigned a unique numerical identifier and in this instance each organisation will be given a pseudonym.

Ethics and governance approvals

These are in process as noted in Figure 1.

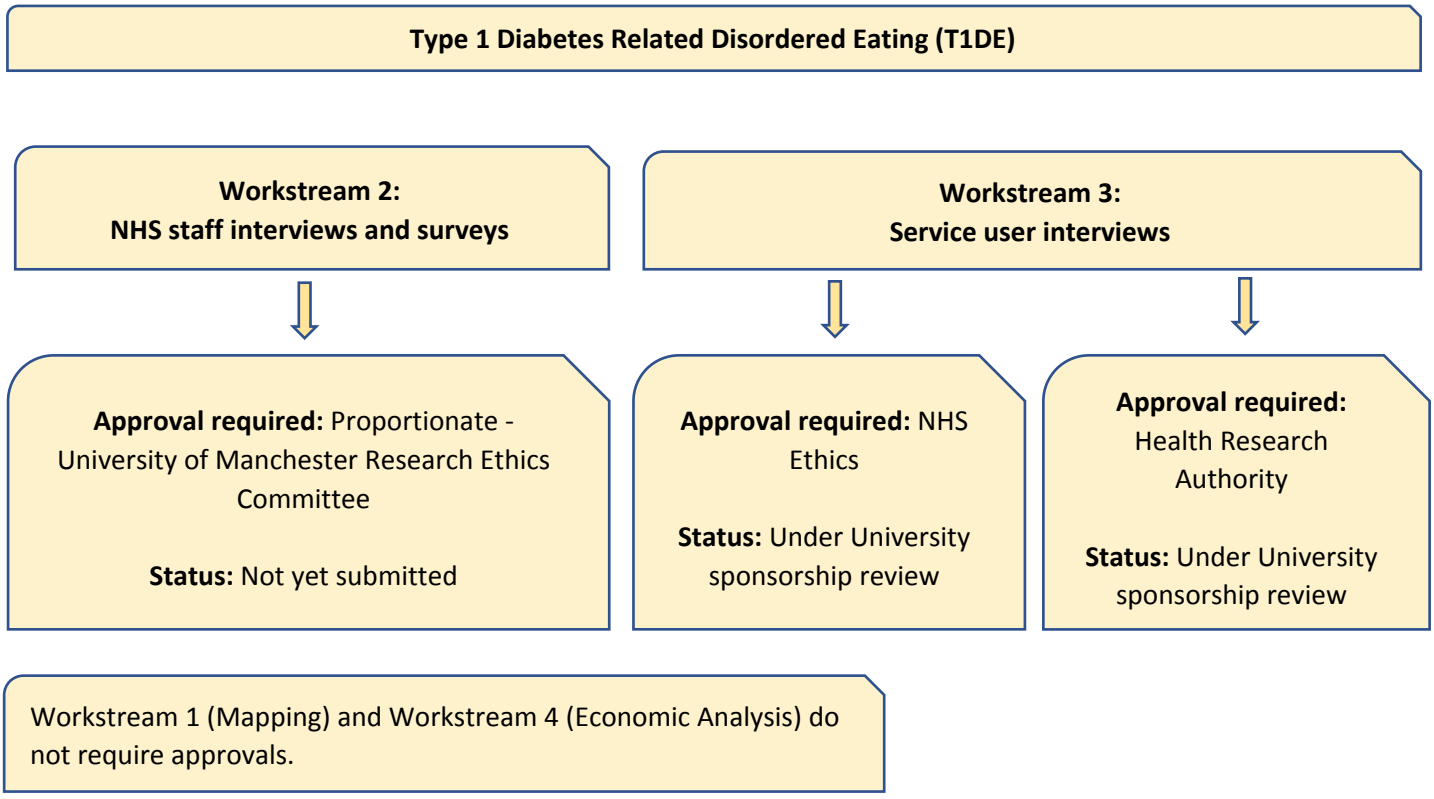

Figure 1: Summary of required approvals and progress to date.

Statement of Indemnity

The University of Manchester has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

Funding

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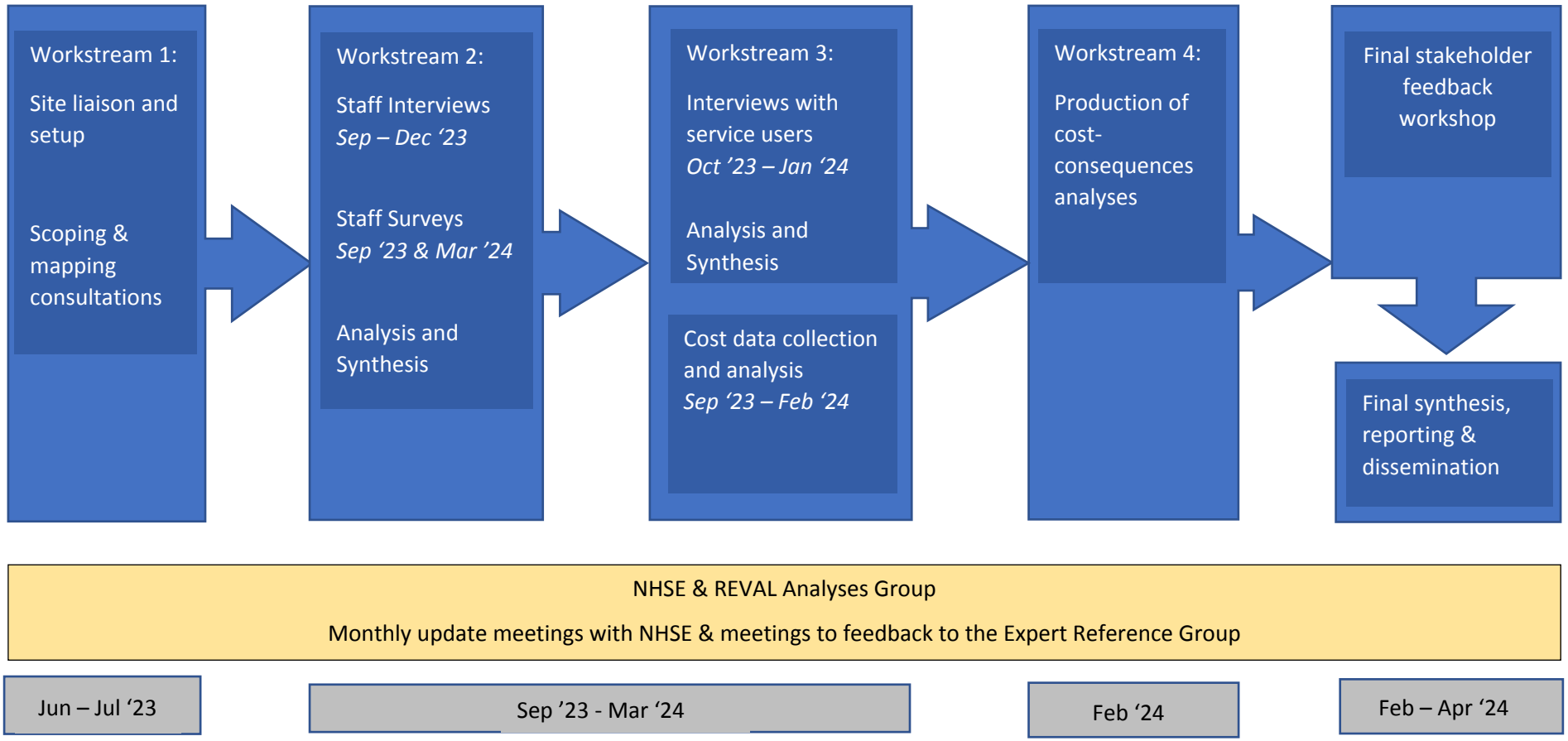
Project timelines



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Appendix 1:

A1. Mapping of key deliverables to proposed evaluation of early and on-going implementation of Type 1 diabetes-related disordered eating services.

Potential deliverables	Source of relevant data from proposed evaluation
Descriptions of important features of Type 1 diabetes-related disordered eating services, with understanding of areas of synergy and variation. Insights into what commissioners want to know about these services to inform decision making.	Workstreams 1 and 2
Insights into barriers and facilitators for service implementation and key features and mechanisms to achieve optimal implementation. Insights into the feasiblity of sustained delivery with appropriate referral and access.	Workstream 2
Understanding whether Type 1 diabetes-related disordered eating service models are acceptable to staff.	Workstream 2
Understanding whether Type 1 diabetes-related disordered eating service models are acceptable to service users.	Workstream 3
Understanding service users experiences of Type 1 diabetes-related disordered eating service models and how they compare with previous experiences.	Workstream 3
Evidence that appropriate numbers/types of users are accessing Type 1 diabetes-related disordered eating service models	NHSE internal analyses
Evidence of clinical benefits that may be expected from the Type 1 diabetes-related disordered eating service model.	NHSE internal analyses
Insights into the cost implications of running Type 1 diabetes-related disordered eating service models.	Workstream 4
Insights into how costs versus impacts relate for the Type 1 diabetes-related disordered eating service model.	Workstream 4