NICE National Institute for Health and Care Excellence

Evidence generation plan for digital technologies for delivering specialist weight-management services to manage weight-management medicine

Implementation support
Published: 26 October 2023
Last updated: 6 March 2024

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Contents

1 Purpose of this document

NICE's assessment of digital technologies for delivering multidisciplinary weight-management services recommends that more evidence is generated while 9 of the technologies are being used in the NHS:

- CheqUp, Gro Health W8Buddy, Juniper, Liva, Oviva, Roczen and Second Nature are recommended for prescribing and monitoring weight-management medicine and delivering multidisciplinary weight-management services for managing overweight and obesity in adults.
- CheqUp, Counterweight, Gro Health W8Buddy, Juniper, Liva, Oviva, Roczen, Second Nature and Weight Loss Clinic are recommended for delivering multidisciplinary weight-management services for managing overweight and obesity in adults when they are not used to prescribe and monitor weight-management medicine.

These technologies can be used once they have Digital Technology Assessment Criteria (DTAC) approval. Three other technologies that were assessed can only be used in research and are not covered in this plan.

This plan outlines the evidence gaps and what real-world data needs to be collected for a NICE review of the technologies again in the future. It is not a study protocol but suggests an approach to generating the information needed to address the evidence gaps. For assessing comparative treatment effects, well-conducted randomised controlled trials are the preferred source of evidence, if these can address the research gap.

The companies are responsible for ensuring that data collection and analysis takes place. Support for evidence generation will be available through a competitive process facilitated by the Office for Life Sciences, pending business case approval. This will be in the form of funding for evidence generation consortia, bringing analytical partners and implementation sites together with companies for evidence generation.

The Department of Health and Social Care's Office for Health Improvement and Disparities has also announced a 2\u2011\year pilot programme evaluating service delivery models to support access to weight-management medicine. NHS England will deliver the programme, with analytical partners commissioned by the National Institute for Health and Care Research. The programme may support evidence generation for technologies

adopted through NHS England's procurement process.

Guidance on commissioning and procurement of the technologies will be provided by NHS England, who are developing a digital health technology policy framework to further outline commissioning pathways.

NICE will withdraw the guidance if the companies do not meet the conditions in section 4 on monitoring.

After the end of the evidence generation period (4 years), companies should submit their evidence to NICE in a form that can be used for decision making. NICE will review all the evidence and assess whether the technologies can be routinely adopted in the NHS.

2 Evidence gaps

This section describes the evidence gaps, why they need to be addressed and their relative importance for future committee decision making.

The committee will not be able to make a positive recommendation without the essential evidence gaps (see section 2.1) being addressed. Companies can strengthen their evidence base by also addressing as many other evidence gaps (see section 2.2) as possible. Addressing these will help the committee to make a recommendation by better understanding the patient or healthcare system benefits of the technology.

2.1 Essential evidence for future committee decision making

Change in weight

Evidence of sustained long-term weight loss is needed to evaluate the benefits for people using the technologies, because obesity is a chronic condition.

Monitoring and reporting adverse events

Obesity is a complex condition and people may have additional comorbidities including mental health issues. The committee had concerns about risk management and safety monitoring of the technologies, particularly in people taking weight-management medicine. Evidence on how the technologies monitor and report adverse events is needed to evaluate the safety of these technologies.

Resource use

To evaluate the cost effectiveness of the technologies, further information is needed on:

- healthcare resource use, including number and type of healthcare appointments, NHS staff time needed to support using the technologies, the cost of the weight-management medicine, and referral to bariatric surgery

- costs associated with implementing and maintaining the use of the technologies in an NHS pathway
- cost estimates for multidisciplinary weight-management services.

2.2 Evidence that further supports committee decision making

Adherence and completion

More evidence is needed on adherence and completion rates for people using the technologies, to:

- assess if adherence has any effect on clinical benefit
- inform future economic modelling
- understand if adherence is different in particular groups.

The reasons for stopping using a technology are also important to understand. Information on patient characteristics is also needed to evaluate differences in access to the technologies and the potential impact on health inequalities.

Health-related quality of life and psychological outcomes

There is a high burden of mental health issues in people with obesity. Additional data collection is needed using specific patient-reported outcome measures on health-related quality of life and for psychological outcomes such as anxiety or depression and eating disorders. This will support evaluation of the technologies' impact on mental wellbeing using consistent outcomes.

3 Approach to evidence generation

3.1 Evidence gaps and ongoing studies

Table 1 summarises the evidence gaps and ongoing studies that might address them. Information about evidence status is derived from the external assessment group's reports; evidence not meeting the scope and inclusion criteria is not included. The table shows the evidence available to the committee when the guidance was published.

Table 1 Evidence gaps and ongoing studies

Evidence gap and technology	Change in weight	Monitoring and reporting adverse events	Resource use	Adherence and completion	Health-related quality of life	Psychological outcomes
CheqUp	Limited evidence	No evidence	No evidence	Limited evidence	No evidence	No evidence
Counter-weight	Limited evidence Ongoing studies	Limited evidence Ongoing study	No evidence	Limited evidence Ongoing studies	Limited evidence Ongoing study	No evidence
Gro Health W8Buddy	Limited evidence	Limited evidence	No evidence	Limited evidence	Limited evidence	No evidence
Juniper	Limited evidence Ongoing study	Limited evidence	No evidence	No evidence Ongoing study	No evidence	No evidence
Liva	Limited evidence Ongoing study	No evidence	No evidence	Limited evidence	Limited evidence Ongoing study	Limited evidence
Oviva	Evidence available Ongoing studies	Limited evidence Ongoing study	No evidence Ongoing study	Evidence available Ongoing studies	Limited evidence Ongoing studies	Limited evidence

Evidence gap and technology	Change in weight	Monitoring and reporting adverse events	Resource use	Adherence and completion	Health-related quality of life	Psychological outcomes
Roczen	Limited evidence	No evidence	No evidence	Limited evidence	No evidence	Limited evidence
Second Nature	Limited evidence Ongoing study	No evidence	No evidence	Limited evidence Ongoing study	No evidence Ongoing study	No evidence Ongoing study
Weight Loss Clinic	Limited evidence	No evidence	No evidence	Limited evidence	No evidence	No evidence

3.2 Data sources

There are data collections with different strengths and weaknesses that could potentially support evidence generation. NICE's real-world evidence framework provides detailed guidance on assessing the suitability of a real-world data source to answer a specific research question.

NHS Digital's Community Services Data Set (CSDS) is a patient-level secondary uses dataset with clinical and operational data collected from publicly funded community services. It includes data from tier 2 and tier 3 weight-management service providers in England and could support evidence generation.

Patient-level data from the CSDS can be linked to other datasets such as NHS Digital's Hospital Episode Statistics (HES) to support the evaluation of outcomes such as adverse events, further hospital appointments and referral to bariatric surgery. But all the outcomes needed to address the evidence gaps may not be available from the CSDS (for example, adherence data collected by the technology) and linking to other sources may not be possible. This may mean that additional data collection is needed.

The CSDS also informs the NHS National Obesity Audit. The audit data could provide supporting contextual information for evaluating cost effectiveness, such as current national uptake and accessibility of multidisciplinary weight-management services and assessment of changes over time.

The quality and coverage of real-world data collections are of key importance when used

in generating evidence. Active monitoring and follow up through a central coordinating point is an effective and viable approach of ensuring good-quality data with broad coverage.

3.3 Evidence collection plan

To address the evidence gaps, a before and after implementation study or a prospective cohort study is suggested.

For either approach to evidence generation, the study should include people who have had a clinical assessment and are referred to multidisciplinary weight-management services for support. The study should compare outcomes between those whose weight-management service is delivered through the digital technologies and those who have treatment with standard care (in-person or remote treatment, or both) without implementation of the technologies. Data should be collected separately for people having:

- weight-management medicine with multidisciplinary weight-management programme support
- multidisciplinary weight-management programme support without weight-management medicine.

For either study design, high-quality data on patient characteristics is needed to correct for any important differences between comparison groups (for example, using propensity score methods) and to assess who the technologies would not be suitable for. Important confounding factors should be identified with input from clinical experts during protocol development. It is important that people in either comparison group are followed up from a consistent start point at which they have been, or would have been, offered care through the digital technology. This should be in line with the intended use of the technology in the clinical pathway. Loss to follow up should be reported, with reasons, over the data collection period. Differences between self-reported and clinically measured weight-loss outcomes are also a potential source of bias, particularly if these vary between comparison groups, so a consistent measure should be used.

It is essential that appropriate safeguarding and risk management processes are in place when generating evidence. The pathway must allow for clinical review before referral to the technology programme. Also, any safety issues and related adjustments to medicine

during the intervention must be flagged to the appropriate teams for onward referral and investigation. Composition of the multidisciplinary team must be reported and should include, or have access to, psychological support.

Data collection should follow a predefined protocol and quality assurance processes should be put in place to ensure the integrity and consistency of data collection. See NICE's real-world evidence framework, which provides guidance on the planning, conduct, and reporting of real-world evidence studies. This document also provides best practice principles for robust design of real-world evidence when assessing comparative treatment effects.

Before and after implementation study

A before and after design allows for comparisons when there is considerable variation across services in the standards and mode of delivery of multidisciplinary weight-management programmes.

After an enrolment period, the data collection period should be long enough to ensure there is 1-year follow-up data for the standard care groups. The digital technology should then be implemented in the service and data collected from new people having support provided through the technologies. In the second observation period, follow up for 2 years is preferable to show if any weight loss is sustained. The study should compare outcomes between those whose weight management is delivered through the digital technologies and those who had treatment with standard care before implementation of the technologies.

This study could be done at a single centre or ideally, replicated across multiple centres. This could show how the technology can be implemented across a range of services, representative of the variety in the NHS. Outcomes may reflect other changes that occur over time in the population, unrelated to the interventions. Additional robustness can be achieved by collecting data in a centre that has not implemented the technology but is as similar as possible (in terms of clinical practice and patient characteristics) to a site where the technology is being used. This could help control for changes over time that might have occurred anyway and could also enable 2-year follow up in a standard care group.

Prospective comparative cohort study

An alternative approach to evidence generation, when sites are sufficiently comparable in

terms of standard and mode of delivery of multidisciplinary weight-management programmes, is a robustly designed and well-conducted parallel cohort comparison study design. In this type of study, data should be collected from patients in healthcare services where the digital technologies are implemented. It should be simultaneously compared with other similar services where the technologies are not being offered. The study should compare outcomes between those whose weight management is delivered through the digital technologies and similar people having treatment at a comparable site that did not implement the technologies.

3.4 Data to be collected

To address the evidence gaps, the following data should be collected. For people who are taking weight-management medicine, baseline is when the medicine is prescribed. For people who are not taking weight-management medicine, baseline is when they are referred for multidisciplinary weight-management support:

- change in weight, at baseline and at 6 months, 1 year and 2 years follow up
- change in body mass index (BMI), at baseline and at 6 months, 1 year and 2 years follow up
- health-related quality of life (for example, EQ-5D) at baseline and at 6 months, 1 year and 2 years follow up
- psychological outcomes (for example, measures for anxiety and depression such as PHQ-9 and GAD-7, and measures assessing eating disorders such as TFEQ-R18, BEDS-7 and EEQ) at baseline and at 6 months, 1 year and 2 years follow up
- safety indicators monitored and occurrence of adverse events, any medicine and intervention-related adverse effects (including physical and psychological effects), increase in BMI, or unexpectedly large or sudden reduction in BMI, new diagnoses of anxiety or depression, incidence of suicide and self-harm, development of eating disorders
- information about the multidisciplinary service provided (composition and frequency and mode of interaction with the person) including NHS grade of staff involved
- programme adherence and completion rates, including reasons for stopping the programme

- weight-management medicine type, dose and prescription date
- medicine adherence, rates and reason for stopping the medicine, including side effects, discontinuation criteria (for example, less than 5% of the initial weight lost after 6 months), reaching predefined weight loss goals
- uptake: information on the number of people accessing multidisciplinary weight-management services (and, when relevant, weight-management medicine) with and without the technology
- information at baseline about potential confounding factors and characteristics that could be associated with reduced access or adherence to multidisciplinary weight-management services (for example, comorbidities, sex, age, ethnicity, disabilities, geographical region, socioeconomic status)
- resource use, including the number and type of healthcare appointments attended, cost of medicine, NHS staff time needed, and rates of referral to bariatric surgery
- costs associated with implementation and maintenance of the technologies, including any training costs
- cost estimates for multidisciplinary weight management service in the NHS.

3.5 Evidence generation period

This will be 4 years to allow for setting up, implementing the technologies, supplying and accessing medicine, data collection, analysis and reporting.

4 Monitoring

The companies must contact NICE:

- within 6 months of publication of this plan to confirm agreements are in place to generate the evidence
- annually to confirm that the data is being collected and analysed as planned.

The companies should tell NICE as soon as possible of anything that may affect ongoing evidence generation, including:

- any substantial risk that the evidence will not be collected as planned
- new safety concerns
- the technology significantly changing in a way that affects the evidence generation process.

If data collection is expected to end later than planned, the companies should contact NICE to arrange an extension to the evidence generation period. NICE reserves the right to withdraw the guidance if data collection is delayed, or if it is unlikely to resolve the evidence gaps.

5 Implementation considerations

The following considerations around implementing the evidence generation process have been identified through working with system partners:

- There is considerable variation in care delivery between multidisciplinary weight-management service providers. Multidisciplinary services included in the study should be considered for their multidisciplinary team composition and monitoring procedures and how well these are likely to reflect national variability of service delivery.
- Duration of support and the criteria for access to the services also varies between different multidisciplinary weight-management services. This is an important consideration for selecting services to ensure that the technologies are suitable for different populations and to ensure sufficient follow up.
- It is uncertain whether data collection in the Community Services Data Set (CSDS) fully represents all weight-management services. But this is expected to improve with more weight-management services registering and submitting data to the CSDS.
- Implementation may have an increased burden on clinical staff, for example, the need to have training ahead of implementation, data collection and follow up.
- The evidence generation process is most likely to succeed with dedicated research staff to reduce the burden on clinical staff, and by using a suitable real-world data source to collect information when possible.
- Evidence generation should be overseen by a steering group including researchers, commissioners, practitioners and representatives with lived experience of obesity and weight-management services.
- Careful planning of approaches to information governance is vital.
- Companies may improve their chances of securing funding by also collecting data on outcomes relevant to other national organisations, for example, work and productivity outcomes.

ISBN: 978-1-4731-7721-5