



LEEDS  
BECKETT  
UNIVERSITY

---

Citation:

Heggie, L and Mackenzie, RM and Ells, LJ and Simpson, SA and Logue, J (2020) Tackling reporting issues and variation in behavioural weight management interventions: Design and piloting of the standardized reporting of adult behavioural weight management interventions to aid evaluation (STAR-LITE) template. *Clinical Obesity*. ISSN 1758-8111 DOI: <https://doi.org/10.1111/cob.12390>

Link to Leeds Beckett Repository record:

<https://eprints.leedsbeckett.ac.uk/id/eprint/6960/>

Document Version:

Article (Published Version)

---

Creative Commons: Attribution 4.0

© 2020 The Authors.

The aim of the Leeds Beckett Repository is to provide open access to our research, as required by funder policies and permitted by publishers and copyright law.

The Leeds Beckett repository holds a wide range of publications, each of which has been checked for copyright and the relevant embargo period has been applied by the Research Services team.

We operate on a standard take-down policy. If you are the author or publisher of an output and you would like it removed from the repository, please [contact us](#) and we will investigate on a case-by-case basis.

Each thesis in the repository has been cleared where necessary by the author for third party copyright. If you would like a thesis to be removed from the repository or believe there is an issue with copyright, please contact us on [openaccess@leedsbeckett.ac.uk](mailto:openaccess@leedsbeckett.ac.uk) and we will investigate on a case-by-case basis.



# Tackling reporting issues and variation in behavioural weight management interventions: Design and piloting of the standardized reporting of adult behavioural weight management interventions to aid evaluation (STAR-LITE) template

Lisa Heggie<sup>1,2</sup> | Ruth M. Mackenzie<sup>1</sup> | Louisa J. Ells<sup>3</sup> | Sharon Anne Simpson<sup>4</sup> | Jennifer Logue<sup>5</sup>

<sup>1</sup>Institute of Cardiovascular and Medical Sciences, University of Glasgow, Glasgow, United Kingdom

<sup>2</sup>Department of Behavioural Science and Health, Institute of Epidemiology and Health Care, University College London, London, United Kingdom

<sup>3</sup>School of Clinical and Applied Sciences, Leeds Beckett University, Leeds, United Kingdom

<sup>4</sup>MRC/CSO Social and Public Health Sciences Unit, Institute of Health and Wellbeing, University of Glasgow, Glasgow, United Kingdom

<sup>5</sup>Lancaster Medical School, Lancaster University, Lancaster, United Kingdom

## Correspondence

Lisa Heggie, Department of Behavioural Science and Health, Institute of Epidemiology and Health Care, University College London, 1-19 Torrington Place, London WC1E 7HB. Email: lisa.heggie.19@ucl.ac.uk

## Summary

In the United Kingdom, the National Institute for Health and Care Excellence make recommendations to guide the local-level selection and implementation of adult behavioural weight management interventions (BWMIs) which lack specificity. The reporting of BWMIs is generally poorly detailed, resulting in difficulties when comparing effectiveness, quality and appropriateness for participants. This non-standardized reporting makes meta-analysis of intervention data impossible, resulting in vague guidance based on weak evidence, reinforcing the urgent need for consistency and detail within BWMI description. STAR-LITE - a 4-section, 119-item standardized adult BWMI reporting template - was developed and tested using a two-phase process. After initial design, the template was piloted using adult behavioural weight management RCTs and currently implemented UK BWMI mapping information to further refine the template and examine current reporting and variance. Overall, reporting quality of weight management RCTs was poor, and large variance across different components of real-world BWMIs was observed. Non-specific guidance and wide variation in adult BWMIs are likely linked to inadequate RCT reporting quality and the inability to perform reliable comparisons of data. Future use of STAR-LITE would facilitate the consistent, detailed reporting of adult BWMIs, supporting their evaluation and comparison, to ultimately inform effective policy and improve weight management practice.

## KEYWORDS

adult behavioural weight management interventions, reporting

This is an open access article under the terms of the Creative Commons Attribution License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited.

© 2020 The Authors. Clinical Obesity published by John Wiley & Sons Ltd on behalf of World Obesity Federation

## 1 | INTRODUCTION

Behavioural weight management interventions (BWMI), employed in an attempt to tackle rising obesity prevalence in adults,<sup>1</sup> aim to facilitate weight loss through intervening on three main topics - diet, physical activity and behavioural change.

### 1.1 | Intervention guidance and barriers to commissioning

In the United Kingdom, commissioners of these 'Tier 2' multicomponent behavioural interventions have identified a 'lack of clear guidance', indicating that current National Institute for Health and Care Excellence (NICE) best practice guidelines are too broad to effectively assist local-level BWMI selection.<sup>2</sup> NICE recommendations aim to direct the delivery of high-quality, effective BWMI, but the supporting evidence - a meta-analysis and systematic review comparing weight management RCTs<sup>3,4</sup> - failed to reliably differentiate between the most effective and ineffective components for weight loss. Authors cited paucity of data and inadequate descriptions of BWMI as barriers to evaluation and, following this, NICE collated a list of 'knowledge gaps' where evidence lacked,<sup>5</sup> including:

- A lack of trials directly comparing BWMI in the United Kingdom
- A lack of evidence on which specific components of a BWMI ensure effectiveness
- A lack of evidence on the effect of sexual orientation; disability; religion; place of residence; occupation; education; socioeconomic position; and social capital on the effectiveness of BWMI and analysis of participants by age and gender
- A lack of evidence as to whether any particular type of training for practitioners leads to more effective BWMI

UK weight management mapping efforts have identified considerable variation across nationally implemented BWMI, with indications that widespread uncertainty regarding best practice amongst those who select interventions for use at local-level is the likely cause.<sup>2,6</sup> The reports highlighted the large inconsistency of outcome reporting by BWMI,<sup>6</sup> with authors identifying the absence of standardized reporting as problematic for data analysis due to heterogeneity.<sup>2</sup>

At present, there are no participant-specific gold standard BWMI.<sup>7</sup> Given the wide variation between currently implemented interventions,<sup>2,6</sup> the placement of participants into appropriately tailored BWMI is crucial to maximize individual success. To adequately support informed decision-making regarding the provision of such care, evidence-based guidelines must be drawn from robust analyses of data. To facilitate accurate assessments of intervention effectiveness and identification of the most beneficial components for specific participants, delivery information and outcome reporting must be clear, complete and transparent for the readers. A prominent barrier to drawing reliable comparisons between BWMI lies within general

reporting styles of intervention delivery, in terms of a lack of detail and uniformity - health intervention descriptive reports are often incomplete and widely varying in structure.<sup>7,8</sup> The consistent reporting of BWMI within both research trial and real-world settings is crucial for successful evaluation. The homogeneous, high-quality reporting of BWMI descriptions would facilitate accurate evaluations of interventions within systematic reviews and meta-analyses - findings of which could inform policy and ultimately improve current clinical practice. Further, consequential resource wastage (ie, time and finances) by the implementation of ineffective interventions following vague recommendations could be mitigated by stronger guidelines.

### 1.2 | Intervention reporting frameworks and templates - development and feedback

Robust frameworks exist within clinical research, created to guide intervention description; tackle low reporting quality within RCTs<sup>8</sup>; avoid biased reporting of trials<sup>9</sup>; and address issues of reporting inconsistency (which consequentially hamper comparison efforts), to ultimately facilitate better-informed decisions by policy makers.<sup>10</sup> Numerous tools have attempted to improve the overall poor quality of description within published interventions, present possibly due to little awareness amongst researchers of what constituted adequate reporting.<sup>11</sup> Transparency from authors is encouraged by 'checklists', provided for reporters to follow as guides - however, most tools do not attempt to standardize reporting structure,<sup>8,9,11,12</sup> allowing great variation in content reported. For example, the SPIRIT 2013 Statement (Standard Protocol Items: Recommendations for Intervention Trials)<sup>12</sup> presented a list of minimum items to be addressed within clinical trial protocols, but does not control for variation in depth-of-detail within intervention descriptions. As reporting guidance has developed, more discipline-specific tools have been created - for example, CONSORT-SPI 2018, an extension of CONSORT 2010, expanded on several items to develop checklist relevance for social and psychological RCTs<sup>13</sup> - but a lack of highly specific reporting recommendations for BWMI persists.

Clinical BWMI commonly do not publish all outcome or delivery information explicitly and there is an absence of consistency in reporting styles between those that have, limiting accuracy of comparisons. In 2009, the National Obesity Observatory created the 'Standard Evaluation Framework for Weight Management Interventions', a project aiming to facilitate future intervention evaluation.<sup>14</sup> A revised version and online data-collection tool (where intervention leads could submit delivery data to the Public Health England database) was produced in 2018, informed by regionally gathered feedback on the earlier edition from relevant users, that is, BWMI commissioners, providers and researchers.<sup>15</sup> A prominent issue with this tool was the general non-specificity of items included - allowing opportunity for variation in responses. Similar to intervention mapping and NICE guidance knowledge gaps, the Standard Evaluation Framework document cited a need for high-quality evidence regarding BWMI effectiveness. The National Obesity Observatory recommended that to further support Standard Evaluation Framework implementation, standardized reporting

templates for BWMI should be created which would specifically assist the expansion of the current evidence-base of BWMI and support rigorous evaluations of effectiveness.

### 1.3 | Aims of the current paper

Despite existing tools, reporting quality across weight management interventions remains poor, persistently limiting the effectiveness of comparisons within research and causing authors to call for standardized guidance on reporting.<sup>16-18</sup> In order to improve overall BWMI reporting quality with regard to consistency, clarity and completeness, an effective and specific solution must be offered. In 2020, a comprehensive, 24-item 'core outcome and corresponding definition/instrument set' gathered using expert consensus was published to improve BWMI outcome reporting.<sup>19</sup> This list of outcomes (defining which should be measured and how) aimed to resolve uncertainty in decision making by presenting BWMI outcome information equally across all interventions. The current paper describes the development and piloting of a template for the standardized descriptive reporting of adult BWMI, to complement this core outcome set. Readily available descriptive data for BWMI is predominantly from lab-based trials or research settings, which may not entirely reflect that of clinical interventions.<sup>20,21</sup> Moreover, this information is found within individual papers and must be deconstructed by readers without a consistently encouraged reporting style or structure. Therefore, the current template will be designed for both clinical BWMI and behavioural weight management RCTs that are implemented in a real-world setting. Template piloting will provide insight into the current variation and reporting quality seen in both, respectively.

## 2 | METHODS

Utilizing a team approach (L.H., R.M.M., L.J.E., S.A.S., J.L.), the template was designed and developed with expertise from areas of obesity and weight management, BWMI implementation, psychology and social care research. Design methodology was planned as a two-phase process.

### 2.1 | Phase 1 - initial template design

This phase was designed to produce a preliminary list of items within an initial template draft, which was generated by one researcher and individually checked by the research team. Available research similar in the aim of guiding intervention reporting was examined using online database search engines (PubMed, Google Scholar, ScienceDirect) to identify items for inclusion within the reporting template. Reference lists of relevant papers were hand-searched for related papers to examine.

The initial design phase brought together several published resources - including similar reporting tools,<sup>11,15,22-24</sup> intervention

mapping reports,<sup>2,6,15</sup> NICE guidance and related commissioner feedback<sup>5,15</sup> - to identify the key components required for detailed capture of BWMI delivery data (Table 1). Template creation intended to complement a pre-defined core outcome set for BWMI reporting,<sup>19</sup> whilst aiming to address gaps in NICE knowledge<sup>5</sup> and areas of uncertainty via specific item inclusion.

### 2.2 | Phase 2 - piloting

The template was piloted using spreadsheet software for ease-of-data-entry and analysis (Microsoft Excel 2016). Three types of BWMI reporting data were gathered:

- Eleven completed, anonymized Scottish mainland health board Tier 2 BWMI provision surveys with the original purpose of investigating BWMI variation<sup>6</sup>
- Twenty-eight published RCTs<sup>7,28-53</sup> (representing 39 individually-piloted behavioural intervention arms) were identified from the systematic review investigating the clinical effectiveness of long-term BWMI conducted to inform NICE Tier 2 guidance<sup>4</sup>
- Nine anonymized national BWMI reports, freely submitted (from 2011 onwards) by respective organizations via the Public Health England obesity evaluation Standard Evaluation Framework data collection tool and archived within the National Obesity Observatory intervention database<sup>22</sup>

Specific inclusion and exclusion criteria for piloted interventions are detailed in Table 2. BWMI data extraction was undertaken by one researcher. Data was systematically entered into the spreadsheet intervention-by-intervention.

Data gathered were used to refine item inclusion and wording, depending on the item's ability to encourage consistent answer specificity with minimal ambiguity. The same researcher analysed reporting quality in currently available RCTs (examined through reporting frequency and depth-of-description of template-specific items) and variance across real-world BWMI (relating to delivery-styles and components) by comparing collected data.

## 3 | RESULTS

STAR-LITE (STANDARDIZED Reporting of adult behavioural weight management InTerventions to aid Evaluation), a BWMI reporting template (Table S1) was divided into four sections - 'Referral Pathway'; 'Intervention Delivery'; 'Intervention Components' and 'Costing', inclusive of 38 main items with corresponding sub-questions (119 items in total).

### 3.1 | Phase 1 - initial template design

The template included conditional, multiple choice and free-text answers as modes of data-capture.

**TABLE 1** Resources used to inform and shape initial template design

1. Template for intervention description and replication (TIDieR) checklist and guide <sup>11</sup>
<ul style="list-style-type: none"> <li>• Items provided a basis for initial template draft to be built upon</li> <li>• For example, 'what', 'who', 'how', 'where'</li> <li>• Layout inspected</li> </ul>
2. NICE best practice guidelines for BWMI <sup>5</sup>
<ul style="list-style-type: none"> <li>• Examined to inform template design and for potential items of inclusion with respect to variation in interventions and areas of uncertainty within reporting</li> </ul>
3. Standard Evaluation Framework <sup>25</sup>
<ul style="list-style-type: none"> <li>• Examined for potential items of inclusion with respect to areas of uncertainty within reporting and variation in interventions</li> <li>• For example, 'essential' and 'desirable' criteria for evaluating a BWMI</li> </ul>
4. Standard Evaluation Framework feedback report <sup>15</sup>
<ul style="list-style-type: none"> <li>• Examined to inform template design with respect to variation in interventions, areas of uncertainty within reporting and barriers to uptake</li> <li>• Provided recommendation for standardized data collection tool</li> </ul>
5. Two-part NICE-affiliated review of current BWMI evidence <sup>3,4</sup>
<ul style="list-style-type: none"> <li>• Comparisons made within the review used as the basis for NICE BWMI guidance (part 1a and part 1b) informed item inclusion</li> <li>• For example, 'delivery style', 'delivery mode' and intervention content</li> </ul>
6. Scottish Tier 2 BWMI mapping survey <sup>6</sup>
<ul style="list-style-type: none"> <li>• Examined for potential items of inclusion, seeking to improve on potential areas of non-specificity relevant to intervention reporting</li> <li>• Layout inspected</li> </ul>
7. Public Health England BWMI mapping report <sup>2</sup>
<ul style="list-style-type: none"> <li>• Provided recommendation for standardized data collection tool</li> <li>• Feedback within mapping report informed important items of inclusion</li> <li>• For example, 'costing'</li> </ul>
8. Standard Evaluation Framework online data collection tool <sup>22</sup> created by the National Obesity Observatory to allow the collection of intervention summary data by practitioners
<ul style="list-style-type: none"> <li>• Items within the data collection tool were examined for potential inclusion, seeking to improve on potential areas of non-specificity relevant to intervention reporting</li> <li>• For example, 'dietary data collected', 'physical activity data collected'</li> </ul>
9. The Coventry, Aberdeen and London - Refined (CALO-RE) taxonomy <sup>24</sup>
<ul style="list-style-type: none"> <li>• Identified and considered for integration within the template to record behaviour change techniques (BCTs) used within interventions</li> </ul>
10. Taxonomy of BCTs used in interventions <sup>26</sup>
<ul style="list-style-type: none"> <li>• Identified and considered for integration within the template to record BCTs used within interventions</li> </ul>
11. The Oxford Food and Activity Behaviours (OxFAB) taxonomy <sup>27</sup>
<ul style="list-style-type: none"> <li>• Identified and considered for integration within the template to record BCTs used within interventions</li> </ul>
12. Consensus on Exercise Reporting Template (CERT) <sup>23</sup>
<ul style="list-style-type: none"> <li>• Examined to inform item inclusion for physical activity component description</li> <li>• For example, type of physical activity involved, generalized or personalized physical activity</li> </ul>

The 'Referral Pathway' section was designed to capture information regarding how participants entered the intervention, eligibility criteria, referral staff and timescale between referral and active weight loss phase participation. 'Intervention Delivery' included geographical data (ie, total area covered by the intervention, number of bases), delivery setting (ie, primary care, community-based), staff involved and number of sessions (in active weight loss phases and self-defined weight maintenance phases). The third section, 'Intervention Components', dealt with intervention content - specifically, the type of dietary, physical activity and behavioural advice delivered. Questions also aimed to capture whether or not diet and physical activity were monitored, and how. The final section - 'Costing' - concerned BWMI financial information, specifically the costs for

delivering the intervention in a real-world setting (and not including research costs).

Initially, a simple check-list style reporting method was implemented for the description of behaviour change technique (BCT) inclusion using the CALO-RE taxonomy.<sup>24</sup> Upon review, it was decided that a simple 'tick-box' data collection approach elicited minimal detail other than presence or absence of each BCT, and STAR-LITE was refined to require additional delivery information for each technique. As mentioned by the CONSORT statement, rigid reporting guidelines may unintentionally encourage interventions to report fictitious information.<sup>9</sup> As such, users were given a trichotomous 'yes', 'no' or 'unsure' option when reporting technique presence. Identified via Scottish weight management provision mapping, an area of

**TABLE 2** Inclusion and exclusion criteria for BWMI used during template piloting phase

Inclusion criteria
Fully completed evaluation ( <i>National Obesity Observatory BWMI only</i> )
Delivered in any setting (ie, community/commercial/primary care/online)
Long-term follow-up of $\geq 12$ months ( <i>RCTs only</i> )
Participants classified as overweight or obese (BMI of $\geq 25$ kg/m <sup>2</sup> and $\geq 30$ kg/m <sup>2</sup> , respectively, or a BMI of $\geq 23$ kg/m <sup>2</sup> in Asian populations) or $\geq 80\%$ of intervention arm was overweight/obese ( <i>RCTs only</i> )
Real-life clinical or research-based BWMI, applicable to transfer into an NHS setting
Provision of care for participants $\geq 18$ years only
Structured, sustained multicomponent BWMI (diet, physical activity, behavioural therapy)
Exclusion criteria
RCT control conditions detailing no intervention; information-only; one-off sessions for discussion with or without issuing of leaflets; 'usual care'
Participants that are pregnant/with disordered eating/with pre-existing medical condition (ie, diabetes, heart failure, uncontrolled hypertension or angina) ( <i>RCTs only</i> )
Use of surgery or medication for weight loss ( <i>RCTs only</i> )
Focus on other lifestyle change (ie, smoking cessation/reduction of alcohol intake)
Non-reporting of a measure of weight loss ( <i>RCTs only</i> )

Note: Inclusion and exclusion criteria for BWMI used for piloting. RCT-only criteria adapted from NICE guidance supporting paper.<sup>3,4</sup>

suggested further investigation was 'how, where and by whom' individual BCTs were delivered.<sup>6</sup> Thus, the final template required users to report frequency of and during which intervention week(s) each technique was delivered, how the technique was delivered, and details of staff involved.

### 3.2 | Phase 2 - piloting

Descriptive BWMI data were recorded during template piloting (Table S2). Real-world BWMI reports were examined for areas of variation; RCTs were examined for reporting frequency (quantified within Tables S3 and S4) and general description quality (in terms of depth-of-detail) within template items.

Multiple choice and free-text items allowing large response variation were amended to conditional answer format. Almost all multiple-choice items were revised to contain additional answer options according to the most commonly encountered data and variation in intervention description.

Overall, real-world BWMI and RCTs fit well into STAR-LITE during piloting, aside from 'Costing' (as only one intervention paper<sup>34</sup> reported financial information) and BCT reporting through CALORE<sup>24</sup> (as few made use of a recognized taxonomy).

### 3.3 | Referral pathway

Most real-world BWMI involved self-referral or healthcare professional referral (ie, GP, nurse) and were open to participants  $\geq 18$  years, of any gender and ethnicity.

Items related to referral personnel (ie, staff or self-referral) and eligibility criteria were generally well reported by RCTs - of all 39 individually reported intervention arms, 37 reported the referral pathway method (ie, 'self-referral' in response to for example, advertisement flyers; healthcare professional referral). Thirty-eight intervention arms reported specific inclusion criteria, 36 reported exclusion criteria and 29 reported pre-participation assessment methods. Few interventions reported the duration between referral and active weight loss phase initiation ( $n = 9$ ) or whether incentives for attending the intervention were offered ( $n = 14$ ).

### 3.4 | Intervention delivery

Real-world BWMI displayed large variance across delivery and setting, with both group-based and 1-to-1 sessions delivered within primary care (eg, general practices, hospitals), leisure centres and workplaces, amongst others. Active weight loss phase sessions varied in total number (generally between 4 and 15 sessions), frequency (mostly weekly or fortnightly) and duration (between 15 and 90 minutes). Wide variation was seen in descriptions of weight maintenance phases, and implementation of these sessions differed in frequency, intensity and delivery mode, if present at all. Real-world interventions varied widely in the type of staff employed (eg, healthcare or physical activity professionals, intervention-trained laypeople) and staff training standards.

Delivery descriptions were reported by all 39 individual RCT interventions but varied greatly in depth of detail. Most indicated total number of sessions, delivery method and average session duration, with higher-quality interventions describing in detail session frequency, number of participants permitted in group-based sessions (if applicable) and delivery setting. Five RCTs specifically indicated a weight maintenance phase but definitions varied, usually with few contact sessions.<sup>31,32,44,46,48</sup> All 39 intervention arms reported some form of staff description, ranging from identification of the job title only to role details; 22 of these noted specific staff training details.

### 3.5 | Intervention components

Dietary advice varied widely across real-world BWMI. 'Healthy eating' guidance (eg, Eatwell Guide) was commonly referenced, although application of other advice (eg, prescribed eating plans, macronutrient recommendations) varied. Components ranged from non-supervised sessions optionally carried out by participants, to weekly 45-60 minutes sessions delivered by a trained instructor. Both were generally self-monitored via diaries. BCT application varied but most included 'goal setting' and 'motivational interviewing'.

Of the 39 RCT intervention arms, 33 reported BCTs employed, however, only 5 - from one paper<sup>37</sup> - used a recognized BCT taxonomy.<sup>26</sup>

Description in the remaining 28 interventions varied from 'behavioural change' to lists of several techniques used. Thirty-six intervention arms mentioned some form of dietary advice delivered to participants; depth of detail ranged from 'balanced diet based on healthy-eating principles' to comprehensive instructions (ie, calorie recommendations, meal replacement items). Twenty of these indicated the staff responsible for delivering dietary advice (including, eg, 'trained dietitian', 'therapist', 'intervention leader'). Thirty-five intervention arms mentioned the physical activity advice delivered - description varied from brief outlines of the benefits of physical activity to details of duration, frequency, type and location. Fifteen RCT interventions reported supervised physical activity sessions, only 11 of which specifically detailed delivery by an exercise professional. Descriptions were unclear as to whether staff were qualified physical activity instructors, as per NICE guidelines.<sup>5</sup> Physical activity and dietary monitoring were reported by 26 and 28 interventions, respectively.

### 3.6 | Costs

Costing information could not be adequately collected due to absence of description across all data sources. Three RCT interventions, from one paper,<sup>34</sup> reported estimated costs per participant as estimated by 'the total annual costs of the intervention (per RCT condition), divided by the total number of participants in the group with measured body mass index at 12 months'.

## 4 | DISCUSSION

We have used multiple intervention mapping exercises, NICE and Standard Evaluation Framework practice guidelines and previously designed reporting frameworks<sup>5,15,25</sup> to identify and select the critical items required to adequately report BWMI for the purposes of future analysis, creating STAR-LITE. Through consideration of high-quality, evidence-based tools and pre-existing evidence of a need for a specific BWMI reporting tool, a robust template was produced.<sup>11,24</sup> A lack of clear guidance regarding intervention specification was identified as a barrier to the commissioning of BWMI.<sup>2</sup> Effective recommendations can only be made in the presence of well-reported RCTs - transparent descriptions of which are needed to inform the evidence-base of 'what works' for specific participants, thus shaping real-world BWMI. STAR-LITE was designed to complement a comprehensive list of core outcomes, developed through expert consensus, that should be reported by both weight management trials and real-world interventions to facilitate comparisons of intervention effectiveness.<sup>19</sup>

### 4.1 | Phase 1 - initial template design: resources and process

STAR-LITE was developed to allow investigation into knowledge gaps identified by NICE through specific item inclusion.<sup>5</sup> For example, evidence surrounding practitioner training is lacking, in relation to which

types may lead to more weight loss. NICE recommends that staff are trained prior to intervention implementation and professional staff development sessions are delivered throughout, but fails to make specific qualification recommendations. Therefore, an item included within the template required the description of staff, their qualifications and experience - details commonly ill-defined within weight management RCT reporting, as shown within piloting.

Taxonomies are a recognized method to assist the reporting of (typically complex) behaviour change interventions and their applied BCTs.<sup>24,54,55</sup> Techniques are coded by a corresponding number which can be reported by those who deliver them, facilitating increased clarity and transparency within intervention reporting.<sup>56</sup> Without the use of a taxonomy, the same BCT could be described by separate interventions in many different ways, causing issue for the comparison of results. For this reason, and due to the challenges of accurate BCT replication within research, CONSORT recommends utilizing a recognized BCT taxonomy to increase clarity and transparency within intervention reporting.<sup>56</sup> By incorporating a widely-used BCT taxonomy,<sup>24</sup> behavioural components can be more accurately described, quantified and their presence or absence compared with other interventions.

STAR-LITE was designed to capture all relevant BWMI delivery data (prompting for information that was found to be frequently non-reported through piloting), whilst aiming for minimal misinterpretation via clear and simple language. Uniformly reported data is encouraged through minimal use of free-text answer options. Free-text answers were permitted for items that could not be adequately detailed using standard multiple-choice answers - here, word counts are suggested to avoid over- and under-reporting between interventions and thus reduce more possible variance. To reduce administration time where possible, simple data collection techniques (ie, multiple-choice 'tick-box' answers; conditional question and answer formatting) attempted to lower user burden, thus increasing the likelihood of compliance across different BWMI organizations. STAR-LITE was initially based on the predominantly free-text answer questionnaire used for Tier 2 and 3 Scottish weight management mapping,<sup>6</sup> which took nine health boards each an estimated 1 hour to complete. The average time for STAR-LITE completion (a larger, more comprehensive tool) by a knowledgeable intervention lead is estimated to be 1-1.5 hours, given the large reduction in free-text answer options and increased use of closed answers, comparatively. The template was designed to be completed once, updated with any intervention changes, and published as an appendix to the corresponding intervention paper as a distinct document detailing BWMI delivery information.

STAR-LITE was structured for simplicity of use - key areas and subsequent items were arranged in chronological order from initial referral to intervention cessation.

### 4.2 | Phase 2 - piloting: variation, reporting quality and template refinement

Piloting had two main purposes - to inform template development and to test STAR-LITE efficacy in data collection from both publicly

implemented clinical and research-trial interventions, ensuring applicability across a range of BWMI. Data collected via piloting offered the opportunity to observe differences in reporting frequency and quality across currently published BWMI.

Through piloting we have observed that overall, behavioural weight management RCT delivery descriptions generally lack consistency or intervention component detail. For example, BCTs (despite being fundamental to BWMI) are poorly described without taxonomy use; minimal session- or staff-specific information is provided; and there is a lack of clear description of the dietary and physical activity components. 'Costing' was the most poorly reported section, yet financial data would assist cost-effective intervention selection when healthcare budgets are restricted. RCTs used were originally gathered for the development of NICE guidelines, which made this resource a high-quality, informative snapshot of trial reporting. Template piloting highlighted large variation in current clinical BWMI - allowed by non-specific NICE guidance - across many delivery factors (ie, setting, total number and duration of sessions, staff employed) and components (eg, advice delivered, presence of supervised physical activity, BCTs used). Notably, areas of large variation were usually those poorly reported within RCTs. Wide variation is likely to persist without clear, precise BWMI delivery guidelines - development of which would be aided by widespread use of STAR-LITE to facilitate uniformed reporting by all BWMI and support reliable comparisons of data.

Reporting standards of clinical data were heavily reliant on the specificity of each original collection tool - as such, reporting quality could not be discussed in comparable depth to RCTs. Non-specificity of items allows for wide interpretation as to which details to include, in what quantity. In light of this, items included within the template were highly specific, with larger questions divided into sub-questions to elicit short, distinct answers. Additionally, within real-world BWMI reports, clinical personnel commonly left answers blank. 'Missing' answers could carry different meaning depending on the reporter, which may confuse research efforts. Unfortunately, in certain interventions, blank answers may have actually indicated 'non-inclusion' rather than non-reporting of included components - without the use of a specific, well-detailed reporting template it was difficult to ascertain which. In future, an electronic version of STAR-LITE could be formatted to force completion through data entry before progression to the next item.

### 4.3 | Possible barriers to uptake and recommendations for future

Creating a new and widely accepted tool is not without hurdles. Intervention personnel, likely already pressured by time constraints, may not see the benefit of devoting up to 1.5 hours to STAR-LITE completion. However, the template was designed to be completed once (and reviewed with any intervention changes) but will subsequently reduce the workload of future users and reduce the possibility of erroneous data extraction by external researchers. Similar,

albeit less specific tools to increase reporting quality exist within research in different formats, for example, checklists and frameworks. STAR-LITE is complementary to such resources, which have tool-specific advantages but lack the explicit structuring required to consistently facilitate uniformed descriptive delivery reporting from BWMI in both research and clinical settings. For example, CON-SORT-SPI 2018 is a checklist that guides reporting specifically for social and psychological intervention trials over 26 different items.<sup>13</sup> 'Item 5a' encourages reporters to describe intervention delivery but does not specifically prescribe structure for these descriptions, allowing opportunity for variation between reporters. Similarly, the SPIRIT 2013 checklist for clinical trials reminds the reporter to describe interventions 'with sufficient detail to allow replication' in 'item 11a'.<sup>12</sup> Here, STAR-LITE can be referred to - completed templates can be presented as an appendix to corresponding intervention papers, covering these items without additional reporter workload. These appendices would be ready-made catalogues of intervention information for those who require it, saving BWMI leads time when delivery descriptions are needed. Additionally, although STAR-LITE contains 119 items in total (38 primary items with related sub-questions), the use of conditional answer formatting means that not all questions will be relevant to every intervention. In future, the development of an electronic form would facilitate faster completion and simpler maintenance, further reducing time-to-complete. Electronic storage of the template would allow simple upkeep by intervention personnel.

To maintain relevance and acceptability over time, flexibility of design is crucial for STAR-LITE due to the developing nature of weight management research. For example, dietary advice has varied significantly in the past decade. Within the next 10 years, presently offered multiple-choice answer options (eg, 'intermittent fasting', 'low carbohydrate diet') may become irrelevant, obsolete and discarded from BWMI, replaced by novel components not yet examined. In future, this will require STAR-LITE reappraisal and review in line with developing research - changes may be necessary to ensure continuous and complete, high-quality reporting. Regularly scheduled reviews of template design will ensure that constant and accurate capture of relevant intervention data is within the capabilities of STAR-LITE. Again, developing STAR-LITE to exist as an e-reporting tool - the products of which could be cited by intervention personnel and linked within papers to direct readers - would facilitate this, by allowing formatting to be modified over time as interventions evolve.

STAR-LITE will be rolled out for use by all BWMI to facilitate detailed reporting of intervention delivery information for evaluation-purposes. Widespread STAR-LITE completion by many intervention teams would result in comprehensive, openly available sets of BWMI delivery data for analysis within future research efforts. We encourage interventions to highlight their use of STAR-LITE within publication materials in order to spread awareness and knowledge about this good practice, thus increasing future uptake by others. Submission of user feedback and comments to support the future development of STAR-LITE would also be encouraged to assist STAR-LITE formatting reviews.



## 5 | CONCLUSION

STAR-LITE, a specifically designed, developed and tested template, could encourage a higher standard of reporting across adult BWMI than is currently seen. With effective, evidence-based directions for implementation resulting from robust meta-analysis of data, real-world BWMI tailored to specific populations would successfully reduce participant obesity prevalence.

### ACKNOWLEDGEMENTS

L. H. and J. L. drafted the manuscript. All authors provided relevant subject area expertise to shape STAR-LITE. R. M. M., L. J. E. and S. A. S. critically reviewed the manuscript, before L. H. and J. L. finalized the manuscript.

### CONFLICTS OF INTEREST

No conflict of interest was declared.

### ORCID

Lisa Heggie  <https://orcid.org/0000-0002-4846-2357>

Louisa J. Ells  <https://orcid.org/0000-0003-0559-4832>

Sharon Anne Simpson  <https://orcid.org/0000-0002-6219-1768>

Jennifer Logue  <https://orcid.org/0000-0001-9549-2738>

### REFERENCES

- Health Survey for England. <https://digital.nhs.uk/data-and-information/publications/statistical/health-survey-for-england/health-survey-for-england-2016>. Published 2016. Accessed May 28, 2018.
- Coulton V, Dodhia S, Ells L, Blackshaw J, Tedstone A. *National mapping of weight management services: provision of tier 2 and tier 3 services in England*. London: Public Health England; 2015.
- Hartmann-Boyce J, Johns D, Aveyard P, et al. *Managing overweight and obese adults: update review. The clinical effectiveness of long-term weight management schemes for adults (review 1a)*, vol. 1. London, UK: NICE (National Institute for Clinical Excellence); 2013:1-163.
- Hartmann-Boyce J, Johns D, Aveyard P. *How components of behavioural weight management programmes affect weight Change: Review 1b*. London, UK: NICE (National Institute for Clinical Excellence); 2013.
- NICE. *Weight management: lifestyle services for overweight or obese adults*. <https://www.nice.org.uk/guidance/ph53>. Published 2014. Accessed May 14, 2018.
- Read S, Logue J. Variations in weight management services in Scotland: a national survey of weight management provision. *J Public Health*. 2016;38(3):e325-e335.
- Nanchahal K, Power T, Holdsworth E, et al. A pragmatic randomised controlled trial in primary care of the Camden weight loss (CAMWEL) programme. *BMJ Open*. 2012;2(3):e000793.
- Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *The Lancet*. 2001;357(9263):1191-1194. [http://dx.doi.org/10.1016/s0140-6736\(00\)04337-3](http://dx.doi.org/10.1016/s0140-6736(00)04337-3).
- Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMC Med*. 2010;8(1):18.
- Williamson PR, Altman DG, Blazeby JM, Clarke M, Gargon E. The COMET (core outcome measures in effectiveness trials) initiative. *Trials*. 2011;12(Suppl 1):A70.
- Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ*. 2014;348:g1687.
- Chan A-W, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med*. 2013;158(3):200-207.
- Montgomery P, Grant S, Mayo-Wilson E, et al. Reporting randomised trials of social and psychological interventions: the CONSORT-SPI 2018 extension. *Trials*. 2018;19(1):407.
- Roberts K, Cavill N, Rutter H. *Standard evaluation framework for weight management interventions*. Oxford, UK: National Obesity Observatory; 2009.
- Public Health England. *Weight management: guidance for commissioners and providers*. <https://www.gov.uk/government/collections/weight-management-guidance-for-commissioners-and-providers>. Published 2017. Accessed May 25, 2018.
- Aceves-Martins M, Robertson C, Cooper D, et al. A systematic review of UK-based long-term nonsurgical interventions for people with severe obesity (BMI  $\geq 35$  kg m<sup>-2</sup>). *J Hum Nutr Diet*. 2020;33:351-372.
- Borek AJ, Abraham C, Greaves CJ, Tarrant M. Group-based diet and physical activity weight-loss interventions: a systematic review and meta-analysis of randomised controlled trials. *Appl Psychol Health Well Being*. 2018;10(1):62-86.
- Sutcliffe K, Richardson M, Rees R, et al. *What Are the Critical Features of Successful Tier 2 Weight Management Programmes for Adults? A Systematic Review to Identify the Programme Characteristics, and Combinations of Characteristics, that Are Associated with Successful Weight Loss*. London: EPPI-Centre. Social Science Research Unit, UCL Institute of Education, University College London; 2016.
- Mackenzie RM, Ells LJ, Simpson SA, Logue J. Core outcome set for behavioural weight management interventions for adults with overweight and obesity: standardised reporting of lifestyle weight management interventions to aid evaluation (STAR-LITE). *Obes Rev*. 2020;21(2):e12961.
- Steele T, Narayanan R, James M, James J, Mazey N, Wilding J. Evaluation of Aintree LOSS, a community-based, multidisciplinary weight management service: outcomes and predictors of engagement. *Clin Obes*. 2017;7(6):368-376.
- Public Health England. *National mapping of weight management services*. <https://www.gov.uk/government/publications/weight-management-services-national-mapping>. Published 2015. Updated February 15, 2020. Accessed February 15, 2020.
- National Obesity Observatory. *Database of interventions*. Public Health England (PHE). <http://webarchive.nationalarchives.gov.uk/20170110170151/https://www.noo.org.uk/core/search>. Published 2016. Accessed May 29, 2018.
- Slade SC, Dionne CE, Underwood M, et al. Consensus on exercise reporting template (CERT): modified Delphi study. *Phys Ther*. 2016;96(10):1514-1524.
- Michie S, Ashford S, Sniehotta FF, Dombrowski SU, Bishop A, French DP. A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: the CALO-RE taxonomy. *Psychol Health*. 2011;26(11):1479-1498.
- Public Health England. *Standard evaluation framework for weight management interventions*. <https://www.gov.uk/government/publications/weight-management-interventions-standard-evaluation-framework>. Published 2018. Accessed May 25, 2018.
- Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. *Health Psychol*. 2008;27(3):379-387.
- Hartmann-Boyce J, Aveyard P, Koshiaris C, Jebb SA. Development of tools to study personal weight control strategies: OxFAB taxonomy. *Obesity*. 2016;24(2):314-320.

28. Appel LJ, Clark JM, Yeh H-C, et al. Comparative effectiveness of weight-loss interventions in clinical practice. *N Engl J Med.* 2011;365(21):1959-1968.
29. Dale KS, Mann JI, McAuley KA, Williams SM, Farmer VLJPJocn. Sustainability of lifestyle changes following an intensive lifestyle intervention in insulin resistant adults: follow-up at 2-years. *Asia Pac J Clin Nutr.* 2009;18(1):114-120.
30. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med.* 2002;346(6):393-403.
31. Eriksson MK, Franks PW, MJPo E. A 3-year randomized trial of lifestyle intervention for cardiovascular risk reduction in the primary care setting: the Swedish Björknäs study. *PLoS One.* 2009;4(4):e5195.
32. Fitzgibbon ML, Stolley MR, Schiffer L, Sharp LK, Singh V, Dyer AJO. Obesity reduction black intervention trial (ORBIT): 18-month results. *Obesity.* 2010;18(12):2317-2325.
33. Foster-Schubert KE, Alfano CM, Duggan CR, et al. Effect of diet and exercise, alone or combined, on weight and body composition in overweight-to-obese postmenopausal women. *Obesity.* 2012;20(8):1628-1638.
34. Hersey JC, Khavjou O, Strange LB, et al. The efficacy and cost-effectiveness of a community weight management intervention: a randomized controlled trial of the health weight management demonstration. *Prev Med.* 2012;54(1):42-49.
35. Heshka S, Anderson JW, Atkinson RL, et al. Weight loss with self-help compared with a structured commercial program: a randomized trial. *JAMA.* 2003;289(14):1792-1798.
36. Jebb SA, Ahern AL, Olson AD, et al. Primary care referral to a commercial provider for weight loss treatment versus standard care: a randomised controlled trial. *Lancet.* 2011;378(9801):1485-1492.
37. Jolly K, Daley A, Adab P, et al. A randomised controlled trial to compare a range of commercial or primary care led weight reduction programmes with a minimal intervention control for weight loss in obesity: the lighten up trial. *BMC Public Health.* 2010;10(1):439.
38. Kuller LH, Gabriel KKP, Kinzel LS, et al. The Women on the Move Through Activity and Nutrition (WOMAN) study: final 48-month results. *Obesity.* 2012;20(3):636-643.
39. Lindström J, Louheranta A, Mannelin M, et al. The Finnish Diabetes Prevention Study (DPS): lifestyle intervention and 3-year results on diet and physical activity. *Diab Care.* 2003;26(12):3230-3236.
40. Mensink M, Blaak EE, Corpeleijn E, Saris WH, De Bruin TW, EJJOr F. Lifestyle intervention according to general recommendations improves glucose tolerance. *Obes Res.* 2003;11(12):1588-1596.
41. Morgan PJ, Lubans DR, Collins CE, Warren JM, Callister RJO. 12-month outcomes and process evaluation of the SHED-IT RCT: an internet-based weight loss program targeting men. *Obesity.* 2011;19(1):142-151.
42. Patrick K, Calfas KJ, Norman GJ, et al. Outcomes of a 12-month web-based intervention for overweight and obese men. *Ann Behav Med.* 2011;42(3):391-401.
43. Penn L, White M, Oldroyd J, Walker M, Alberti KGM, JCBph M. Prevention of type 2 diabetes in adults with impaired glucose tolerance: the European Diabetes Prevention RCT in Newcastle upon Tyne, UK. *BMC Public Health.* 2009;9(1):342.
44. Rejeski WJ, Brubaker PH, Goff DC, et al. Translating weight loss and physical activity programs into the community to preserve mobility in older, obese adults in poor cardiovascular health. *Arch Intern Med.* 2011;171(10):880-886.
45. Rock CL, Flatt SW, Sherwood NE, Karanja N, Pakiz B, Thomson CAJJ. Effect of a free prepared meal and incentivized weight loss program on weight loss and weight loss maintenance in obese and overweight women: a randomized controlled trial. *JAMA.* 2010;304(16):1803-1810.
46. Ross R, Lam M, Blair SN, et al. Trial of prevention and reduction of obesity through active living in clinical settings: a randomized controlled trial. *Arch Intern Med.* 2012;172(5):414-424.
47. Silva MN, Vieira PN, Coutinho SR, et al. Using self-determination theory to promote physical activity and weight control: a randomized controlled trial in women. *J Behav Med.* 2010;33(2):110-122.
48. Stevens VJ, Corrigan SA, Obarzanek E, et al. Weight loss intervention in phase 1 of the trials of hypertension. *Prevention.* 1993;153(7):849-858.
49. Stevens VJ, Obarzanek E, Cook NR, et al. Long-term weight loss and changes in blood pressure: results of the Trials of Hypertension Prevention, phase II. *Ann Intern Med.* 2001;134(1):1-11.
50. Vermunt PW, Milder IE, Wielaard F, De Vries JH, Van Oers HA, GPJDC W. Lifestyle counseling for type 2 diabetes risk reduction in Dutch primary care: results of the APHRODITE study after 0.5 and 1.5years. *Diabetes Care.* 2011;34(9):DC\_102293.
51. Villareal DT, Chode S, Parimi N, et al. Weight loss, exercise, or both and physical function in obese older adults. *N Engl J Med.* 2011;364(13):1218-1229.
52. Vissers D, Verrijken A, Mertens I, et al. Effect of long-term whole body vibration training on visceral adipose tissue: a preliminary report. *Obes Fact.* 2010;3(2):93-100.
53. Wadden TA, Volger S, Sarwer DB, et al. A two-year randomized trial of obesity treatment in primary care practice. *N Engl J Med.* 2011;365(21):1969-1979.
54. Michie S, Hyder N, Walia A, West R. Development of a taxonomy of behaviour change techniques used in individual behavioural support for smoking cessation. *Addict Behav.* 2011;36(4):315-319.
55. Michie S, Whittington C, Hamoudi Z, Zarnani F, Tober G, West R. Identification of behaviour change techniques to reduce excessive alcohol consumption. *Addiction.* 2012;107(8):1431-1440.
56. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Ann Behav Med.* 2013;46(1):81-95.

## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

**How to cite this article:** Heggie L, Mackenzie RM, Ells LJ, Simpson SA, Logue J. Tackling reporting issues and variation in behavioural weight management interventions: Design and piloting of the standardized reporting of adult behavioural weight management interventions to aid evaluation (STAR-LITE) template. *Clin Obes.* 2020;e12390. <https://doi.org/10.1111/cob.12390>