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Title Page

Title: Why Consistent Completion Criterion are Required in Childhood Weight Management Programmes

Abstract

Objectives: Current research in the field of childhood weight management (WM) effectiveness is hampered by inconsistent terminology and criterion for WM programme completion, alongside other engagement-related concepts (e.g. adherence, dropout, and attrition). Evidence reviews are not able to determine conclusive intervention effectiveness because of this issue. This study aims to quantify how various completion criterion impact upon on: 1) the percentage of WM completers; 2) the standardised Body Mass Index (BMI SDS) reduction; and 3) the predictors of WM completion.

Study Design: A methodological, sensitivity analysis to examine how differential completion criteria affect programme outcomes and predictors.

Methods: Secondary data of 2948 children were used. All children attended a MoreLife WM programme between 2009 and 2014. The completion criterion was incrementally adjusted by 10% (i.e. completer attends 10%, 20%, 30%... of sessions) for research aims 1-2, with the percentage of completers and change in BMI SDS calculated at each increment. For aim 3, the stability (strength, direction, and significance) of the predictors were examined when using the completion criterion of four alternative studies against our previous study (completion ≥70% attendance).

Results: The volume of programme completers decreased in a linear manner as the completion criterion became more stringent (i.e. 70-100% attendance). The change in BMI SDS conversely became incrementally greater. The strength, direction, and significance of the predictors was highly dependent on the completion criterion; the odds ratio varied by 24.2% across a single predictor variable (delivery period). The degree of change is evidenced in the paper.

Conclusions: Inconsistent completion criterion greatly limits the synthesis of programme effectiveness, and explains some of the inconsistency in the predictors of engagement. Standardised criterion for engagement-related terminology are called for.

Key words: Engagement; Completion; Standardised Reporting; Health Improvement Programmes

Introduction

Weight management (WM) programmes have been implemented globally to tackle the obesity epidemic. These programmes are often multifaceted interventions which aim to improve the dietary- and physical activity- behaviours of the participant over a period of time¹. Participants, particularly in the United Kingdom, attend WM programmes weekly or bi-weekly and programmes can be either group-based or one-to-one¹. This approach is adopted for the treatment of both overweight and obesity. As obesity becomes more severe and co-morbidities start to present (e.g. hypertension, sleep apnoea, or impaired glucose tolerance), multi-disciplinary teams of experts are used; including psychologists, physicians, dieticians, physiotherapists, and physical activity specialists¹. Whilst guidance – such as that of the National Institute for Health and Care Excellence (NICE) – has provided WM programmes with recommendations around design components¹, programmes remain diverse in terms of treatment intensity, frequency, duration, and type. Whilst this approach is consistent in adult and childhood populations, this paper will centre around childhood WM programmes.

The effectiveness of childhood WM programmes is not conclusive. A reduction in age and gender standardised Body Mass Index (BMI SDS) and the proportion of participants completing a WM programme are frequently used as primary outcome measures, especially by programme commissioners (i.e. those purchasing the programmes)¹⁻³. With that in mind, researchers have conducted systematic reviews to identify effective WM strategies and programme design components⁴⁻⁶. However, the results of such syntheses are often constrained due to inconsistent terminology and criteria used to define participant engagement; that is, the synonymous use of terms (e.g. dropout, non-completion and attrition) and the non-standardised criteria used to classify participants accordingly (i.e. criterion used to classify completion). For example, it is not possible to compare the outcomes of completers if completion is defined as >50% attendance in programme A and being present in the final session of programme B. This issue is also apparent in other health-related disciplines: anxiety and depression management⁷, type 2 diabetes management⁸, and substance abuse treatment⁹.

In the context of WM, Miller and Brennan¹⁰ identified 27 studies that defined attrition, ten of which additionally defined programme completion. These studies included both adult and childhood populations. The results indicate that no consistent criteria and definition for attrition or completion was adopted amongst the studies¹⁰. Dhaliwal and colleagues¹¹ conducted an integrated review aiming to synthesise the predictors and reasons for participant attrition in childhood WM. In the review of 23 studies, the definitions for attrition varied greatly and the predictors of dropout were inconsistent. This inconsistency was mainly attributed to the inconsistent definitions of attrition and dropout¹¹. These papers highlight the difficulty in synthesising information from multiple sources, and both papers call for standardised definitions and criteria for engagement-related terminology^{10,} ¹¹. In a previous study, we used the term *engagement* to describe a family's level of participation in a programme; this term was used to overarch related terminology (e.g. completion, dropout, retention)¹². Consistent definitions and criteria for engagement-related terminology across health improvement interventions would improve the external validity of individual studies, and in addition, enable researchers and commissioners to draw robust conclusions about effective interventions and intervention components^{10, 11, 13}. In doing so, intervention staff could refine current intervention practices, thus improve programme outcomes and cost-effectiveness.

In the UK, several government-endorsed documents provide guidance for evaluating WM interventions^{1, 3, 14}. These guidelines have the capacity to standardise the reporting and monitoring of engagement-related metrics. At present, there is no agreement between these documents on

how to classify a participant as a completer; the Department of Health suggest 60% attendance¹⁴, whilst the Public Health England Obesity Knowledge and Intelligence Team (formerly the National Obesity Observatory) recommend a threshold of 75% attendance³. Moreover, both cut points are arbitrary and are not based on academic rigour or empirical evidence. NICE note the importance of monitoring attendance and completion rates, but offer no guidance on how to classify completion¹. The reason for such inconsistencies may easily be explained: 1) the completion criteria may be defined by the programmes or programme commissioners themselves; 2) completion and attendance metrics are overshadowed by weight-related outcomes; or 3) programmes differ so vastly in design that a consistent criterion is not feasible.

Notwithstanding these arguments, the impact of various criterion for programme completion has not yet been examined, and past arguments are grounded in logic-based speculation rather than empirical evidence. As such, this paper has three aims: to investigate the impact of an incrementally stringent completion criterion on the percentage of participants completing a childhood WM programme (Aim 1), the mean change in BMI SDS amongst completers (Aim 2), and moreover, to document how four alternative completion criterion may affect the predictors of programme completion (Aim 3). We anticipate that these aims, and the respective findings, will transcend into other health-related disciplines.

Methods

Data

Secondary data of 2948 MoreLife participants were used. The process of data collection, collation and cleansing have been reported previously¹². In brief, participants were mainly female (54.6%), aged 10.44±2.80 years, with a BMI of 25.99±5.79kg/m² (BMI SDS: 2.48±0.87 units), and predominantly of white ethnicity (70.52%). Ethical approval was provided by Leeds Beckett University Faculty Research Ethics Committee (*ref*: 4869) and all participants assented/consented for their data to be used.

MoreLife

MoreLife delivers WM programmes to families in the UK. Families must have a child (aged 4-17 years) with overweight or obesity (BMI SDS \geq 91st centile¹⁵) to enrol onto a programme. Programmes last 10-12 weeks, with families attending one, 2-hour session per week. Parents and children attend together but participate in separate, concurrent sessions. Programmes were delivered in 14 Local Authorities across the UK and all programmes followed a similar protocol. Programmatic details have been reported elsewhere using the Template for Intervention Description and Replication (TIDieR)^{12, 16}.

Participant Attendance

Session-by-session participant attendance was determined through the presence of a weekly child weight recording. The MoreLife protocol stipulates that weight (kg) is collected weekly if the child is present in the programme session. The percentage of attendance was calculated as:

(sessions attended/sessions available) X 100

Completion Criterion

Programme completion was classified at MoreLife as attending ≥70% of sessions – this criterion was chosen as it falls between the Department of Health¹⁴ and the Public Health England Obesity Knowledge and Intelligence Team³ cut points. In addressing aims 1 & 2, the completion criterion was incrementally adjusted by 10% from 0% to 100%. All analyses were re-run at each 10% increment to determine the percentage of completers (i.e. participants whose attendance surpasses the criterion) and the mean change in BMI SDS for completers (i.e. difference between the first measurement and the last measurement). For aim 3, the completion criterion of the original study¹² was altered to mirror those used in other studies which have explored the predictors of non-completion and dropout¹⁷⁻²³. In short, the third aim assesses the difference in the strength and magnitude of the predictors when adopting a range of alternative completion criteria. Table I displays the four alternative criterion in addition to that used at MoreLife (Model 1).

[INSERT TABLE I]

BMI SDS

BMI was calculated as height (m)/weight (kg)². BMI was subsequently standardised to account for age and gender using UK-specific growth reference data¹⁵. One change in BMI SDS was recorded per participant so long as they attended two or more sessions. This change value reflects the difference between the BMI SDS at the first observation and the BMI SDS at the last observation. One may expect that as the completion criterion increases – and a larger proportion of programme attendance is required to complete – the mean change in BMI SDS amongst completers will increase. This paper will demonstrate the extent to which this occurs.

Statistical Analysis

The analyses in this study were two-fold, whereby a different analytical method was applied for aims 1-2, and for aim 3. For aim 1, frequency statistics were used to calculate the percentage of participants completing the programme when completion was defined as $\geq 10\%$, $\geq 20\%$, $\geq 30\%$... $\geq 90\%$ attendance. Similarly, aim 2 utilised descriptive statistics to evidence the mean change in BMI SDS amongst completers at each 10% criterion increment. The outcomes of these analyses (percentage of completers and mean change in BMI SDS) at each criterion increment were plotted on a scatter graph. It is important to note that all participants were recoded as a completer or non-completer at each increment dependent upon their percentage of attendance.

For the third aim, a multivariable logistic regression model (see Nobles *et al.*¹²) - which investigated the predictors of completion - was re-run using each of the four alternative completion criterion (Table I). Thus, the independent variables in the four alternative models were consistent with the original model¹². The dependent variable differed in the four alternative models, whereby all participants were recoded as a completer or non-completer to align with the respective criterion. Six independent variables were entered into the models using a forced-entry method (rationale for variable selection previously reported¹²): Ethnicity (white/white British or non-white/non-white British), Indices of Multiple Deprivation score (proxy for socioeconomic status), baseline BMI SDS, programme year (2009 to 2014 [categorical]), group size (Small [<20 participants] or Large [≥20 participants]), and delivery period (January-, April-, or September- intake). The six variables included in the regression models were only utilised to exemplify the degree to which the magnitude, direction, and significance of the OR can vary under alternative completion criterion.

<u>Results</u>

Percentage of Completers

Programme completion was defined as \geq 70% attendance, in which MoreLife achieved a 47.1% completion rate¹². At any given criterion, the subset of participants includes all those in the most stringent criterions, and therefore a monotonic increasing relationship is to be expected - as observed in Figure 1. When the criterion for completion becomes more stringent (i.e. completion classified as \geq 80% or \geq 90% attendance), fewer participants complete the programme. For example, when completion is classified as \geq 20% attendance, 85.9% of participants complete the WM programme, whilst 34.4% complete when the criterion is set at \geq 80% attendance. These results illustrate the percentage of participants that could be anticipated to complete a programme using any given criterion. The relationship between data points is somewhat linear (Figure 1).

Change in BMI SDS

Using the MoreLife completion criterion, the mean reduction amongst completers was 0.15 units. As anticipated, when participants are required to attend a greater proportion of the WM programme to be classified as a completer (and subsequently the percentage of participants completing the programme reduces), the mean change in BMI SDS for completers increases (Figure 2). More stringent criterion resulted in a greater mean reduction in BMI SDS. Figure 2 can be used to estimate the mean change in BMI SDS when adopting a specific completion criterion. These outcomes represent the mean change in BMI SDS amongst all participants with an attendance greater than the given criterion.

The change in BMI SDS (± SD) and the number of participants completing the programme for each incremental completion criterion are available in online supplement I.

[INSERT FIGURE 1 and FIGURE 2]

Predictors of Completion

Ethnicity, Indices of Multiple Deprivation score, baseline BMI SDS, programme year, group size, and delivery period were entered into the five regression models as independent variables. The ORs for the original model and the four alternative models are presented in Table II. An OR of greater than one indicates that the odds of an event (e.g. completion) occurring increase as the predictor increases, with values below one signifying reduced odds of the event occurring as the predictor increases.

Table II highlights that the magnitude and the direction of the OR are affected by the completion criterion, with the magnitude of the OR differing by up to 24.2% when compared to the original model (see model 4, April intake; value represents the percentage change between the OR of the original model and model 4). Ethnicity appeared most affected by the alternative completion criterion. Model 4 (completion defined as attending all session) indicated that the odds of not-completing the programme were increased by 24% if participants were of non-white ethnicity compared to the original model. However, in model 5 the likelihood of completing the programme were greater for those of non-white ethnicity when completion was defined as attending the last WM session. All results for ethnicity remained non-significant. The magnitude and direction of the

OR for baseline BMI SDS, and the magnitude of the OR for group size, also varied substantially between models (Table II).

The significance (*p*-value) of the predictors was further impacted by the completion criterion, and variables classified as significant ($p \le 0.05$) were inconsistent between models (Table II). For example, group size was a significant predictor in the original model (model 1: completers attend $\ge 70\%$ WM sessions) which then became a non-significant predictor in model's 3, 4, and 5. The OR of programme year and the significance of delivery period (April intake) remained somewhat stable across the five models. However, the results of this analysis suggest that the magnitude, direction, and significance of predictive variables are greatly affected by the completion criterion.

To determine if differences among the models were due to selection bias, the baseline demographics of completers were examined for each alternative criterion (online supplement II). The results indicate minimal heterogeneity between baseline demographics – thus, the sub-samples of completers are representative of the total sample. One exception prevailed, that the percentage white participants completing the programme was higher using the fourth criterion. Results relating to this variable and model should be interpreted with slight caution.

[INSERT TABLE II]

Discussion

Garfield (1989) stated that "the use of varying definitions and criteria of dropouts or premature terminators makes it difficult to compare studies and to secure meaningful generalizations..., the extreme variability among these operational definitions leads to chaos"^{24, 25}. Since then, others have also argued the pertinence of this hypothesis^{11, 13, 26}. This study not only confirms this hypothesis, but it exemplifies the extent to which outcomes [amongst completers] change in light of various completion criterion. The inconsistent criteria for engagement-related terms could explain why the magnitude, direction and significance of the predictors are inconsistent. The predictors of completion varied when applying one of the five various criterion in this study. These findings evoke a cross-discipline call to action: standardised definitions and criteria are urgently required to ensure that studies have strong external validity, and can collectively be synthesised appropriately – doing so will help advance our knowledge of intervention effectiveness.

A reduction in BMI SDS is frequently used as the primary outcome measure for a WM programme, with the level of engagement or number of programme completers viewed as secondary ¹⁻³. Given the importance of these measures – and the degree to which reported outcomes affect the likelihood of service commissioning – differential completion criterion could be used to either compensate "poor" results or overstate "positive" results. For example, an undemanding completion criterion (e.g. ≥40% attendance) would result in a high proportion of programme completers – 73.3% in this instance. Albeit that these results change in the anticipated direction, this study demonstrates the degree to which WM outcomes can either be masked or magnified by various completion criterion.

Previous research has grappled with inconsistent terminology and criteria when looking to synthesise outcomes – be those BMI SDS, completion rates, or the predictors of engagement. There has been a call to action for the measurement and reporting of attrition¹⁰, however we would suggest a further step; identifying, defining and standardising *all* engagement-related terminology. A difference exists between the terms non-completion (i.e. those who do not complete^{25, 27, 28}),

dropout (i.e. a participants' decision, voluntary or involuntary, to withdraw²⁹), and attrition (i.e. the progressive reduction of a cohort/group³⁰), yet they are frequently used synonymously in the literature and included together in systematic reviews^{10, 11, 26}. Compounding the issue, studies have indicated that different variables predict different engagement trajectories (e.g. completion, sporadic attendance, and dropout)^{12, 25}, and so the predictors of non-completion could be very different to those of dropout. That said, research aiming to predict engagement trajectories is of fundamental importance, and future work needs to identify variables which underlie and explain participant engagement (e.g. participant expectations, social support, and relationships with staff members).

Future directions and application of findings

For practitioners, specifically programme commissioners, this research identified the percentage of participants that are likely to complete a programme using any given completion criterion, and furthermore, what change in BMI SDS may be realistically achievable for completers attending a similar up scaled, community-based childhood WM programme.

For others working in the field of engagement, or intervention design and evaluation more broadly, this paper offers a starting point for standardising programme completion. It was possible to conduct these analyses due to weekly attendance data (through proxy recording of weekly weight measurements) being collected. The upkeep and prioritisation of attendance records is a key, and fundamental first step, to progressing in this field. Session-by-session attendance data will enable researchers to effectively analyse programme outcomes and in addition, heighten the external validity of such findings. We anticipate that this approach would be feasible and suitable to wide-ranging interventions, irrespective of the health-related focus.

It is hoped that this study brings stakeholders (i.e. commissioners, providers, and programme participants etc...) and researchers together to discuss the standardisation of engagement-related terminology. It is imperative that both groups work collaboratively to develop a set of accessible and adoptable definitions and criteria. Without such collaboration, any proposed definitions and criteria may not be suitable for their intended application. This study has augmented the rationale for moving in such a direction and offered a feasible first step - the collection of session-by-session attendance data.

Limitations

The findings of this study originate from a large and representative, UK-wide data set – with MoreLife being one of the UK's largest providers of childhood WM programmes. That said, this limits the application of these findings to other settings (e.g. clinically-based WM, adult WM, health improvement interventions). It would therefore be beneficial to extrapolate the current analysis methodology to other settings, data sets, and engagement-related terms. It is hypothesised that the findings of our study would transcend across disciplines and terms, and heighten the rationale for standardising the approach to collecting and reporting engagement-related data. The use of consistent criterion for engagement-terms would facilitate the synthesis of predictive variables and intervention effectiveness.

Whilst this study acknowledges that consistent reporting is needed to progress in the field of engagement research, we do not propose a universal definition and classification for engagement-related terms. Indeed, the criterion used for programme completion in the previous study¹² was based on two guidance documents, the Standard Evaluation Framework³ and the best practice guidelines for Tier 2 services¹⁴. How to gather consensus on engagement criteria, and moreover if

consensus is possible, will be a significant future challenge to overcome. To progress, we recommend capturing session-by-session attendance data as an important first step. A second step is to bring together a range of researchers and stakeholders to define a range of engagement-related terminology. The use of sessional attendance data should be used as a foundation for these definitions and criteria; it provides a sensitive measure of engagement, and enables a range of criteria to be developed.

Conclusion

The criterion used to classify engagement-related terminology is strongly associated with programme outcomes and the predictors of completion. The programme outcomes shared a somewhat linear relationship with the incremental completion criterion – showing no plateau in either the mean change in BMI SDS or the percentage of completers. The OR (and significance) of the predictors were also demonstrated to differ in strength. This study therefore reaffirms the conclusions of others; that standardised terminology and criteria for engagement are needed, and that the continued use of inconsistent terminology will only hinder the progress of understanding effective approaches to WM and health-improvement interventions. In an era of diminishing Public Health budgets and an increased expectation to meet client needs, means of enhancing health-improvement services are ever more important. This paper offers one such example on how to improve these services.

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Figure Legends

Figure 1: Percentage of Participants Completing by Alternative Completion Criterion Red line represents the completion criterion used by MoreLife (≥70% attendance) All participants recoded as a completer or non-completer at each criterion increment

Figure 2: Change in BMI by Alternative Completion Criterion

Red line represents the completion criterion used by MoreLife (≥70% attendance) All participants recoded as a completer or non-completer at each criterion increment

Table I: Alternative Completion Criterion

Model	Completion criterion	Reference
1	Attend ≥70% of the WM programme sessions	12
2	Attend ≥50% of the WM programme sessions	18
3	Attend the first and last session of the WM programme	19, 20
4	Attend all sessions of the WM programme	21
5	Attended the last session of the WM programme.	22, 23

Indonondont voriables	Model 1 ^ª		Model 2 ^b		Model 3 ^c		Model 4 ^d		Model 5 ^e		
independent variables	OR	95% CI	OR	95% CI	OR		95% CI	OR	95% CI	OR	95% CI
Ethnicity†	1.03	0.84, 1.26	0.90	0.73, 1.11	1.09		0.88, 1.35	1.24	0.89, 1.71	0.84	0.68, 1.03
IMD score	1.01 *	1.00, 1.01	1.01 *	1.00, 1.01	1.00	*	1.00, 1.01	1.01 *	1.00, 1.02	1.00	1.00, 1.01
Baseline BMI SDS	1.11 *	1.02, 1.21	1.07	0.97, 1.17	1.09	*	1.00, 1.19	0.96	0.84, 1.11	1.13 *	* 1.04, 1.11
Programme year†	1.13 **	[•] 1.07, 1.20	1.18 **	1.10, 1.26	1.11	**	1.04, 1.18	1.15 **	* 1.05, 1.26	1.17 *	* 1.10, 1.13
Group size†	1.21 *	1.03, 1.42	1.24 **	1.05, 1.47	1.01		0.86, 1.19	1.26	0.98, 1.63	1.06	0.91, 1.21
Delivery period†	-	-	-	-	-		-	-	-	-	-
January intake	Reference period										
April intake	1.28 **	[•] 1.08, 1.53	1.23 *	1.02, 1.48	1.42	**	1.18, 1.70	1.60 **	* 1.19, 2.14	1.48 *	* 1.24, 1.28
September intake	1.26 *	1.05, 1.52	1.22 *	1.00, 1.49	1.16		0.96, 1.41	1.16	0.88, 1.54	1.27 *	* 1.05, 1.26

Table II: Predictors of Completion using Alternative Criteria

Independent variables are consistent in all models and the dependent variable differs. All participants (*n* = 2948) were used in each model, with the number of completers varying dependent on the completion criteria.

^a Completion defined as ≥ 70% attendance (*n* = 1387 completers [47.1% completion rate, mean change in BMI SDS = -0.15 units]). Original model used previously [12].

^b Completion defined as \geq 50% attendance (*n* = 1984 completers [67.3% completion rate, mean change in BMI SDS = -0.13 units])

^c Completion defined as attendance at the first and last session (n = 1142 completers [38.7% completion rate, mean change in BMI SDS = -0.15 units]) ^d Completion defined as attendance at all sessions (n = 328 completers [11.1% completion rate, mean change in BMI SDS = -0.20 units])

^e Completion defined as attending last sessions (n = 1488 completers [50.5% completion rate, mean change in BMI SDS = -0.14 units])

Note: To calculate the percentage change between the OR of the original model (OR_o) and model X (OR_x) = $(OR_x - OR_o) / OR_o$

+Categorical variable

*p ≤ 0.05, ** p ≤ 0.01