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Assessing treatment-as-usual provided to control groups in adherence trials: Exploring the use of an open-ended questionnaire for identifying behaviour change techniques

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***Objective*:** Reporting guidelines call for descriptions of control group support in equal detail as for interventions. However, how to assess the active content (behaviour change techniques (BCTs)) of treatment-as-usual (TAU) delivered to control groups in trials remains unclear. The objective of this study is to pre-test a method of assessing TAU in a multicentre cost-effectiveness trial of an HIV-treatment adherence intervention.
***Design*:** HIV-nurses ($N = 21$) completed a semi-structured open-ended questionnaire enquiring about TAU adherence counselling. Two coders independently coded BCTs.
***Main outcome measures*:** Completeness and clarity of nurse responses, inter-coder reliabilities and the type of BCTs reported were examined.
***Results*:** The clarity and completeness of nurse responses were adequate. Twenty-three of the 26 identified BCTs could be reliably coded (mean $\kappa = .79$; mean agreement rate = 96%) and three BCTs scored below $\kappa = .60$. Total number of BCTs reported per nurse ranged between 7 and 19 ($M = 13.86$, SD = 3.35).
***Conclusions*:** This study suggests that the TAU open-ended questionnaire is a feasible and reliable tool to capture active content of support provided to control participants in a multicentre adherence intervention trial. Considerable variability in the number of BCTs provided to control patients was observed, illustrating the importance of reliably collecting and accurately reporting control group support.

Keywords: treatment-as-usual; randomised controlled trial; control group; behaviour change techniques

Introduction

Health behaviour change interventions are usually multifaceted, and may include a range of active ingredients commonly referred to as behaviour change techniques (BCTs, Abraham, Kelly, West, & Michie, 2009; Abraham & Michie, 2008;

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Bartholomew, Parcel, Kok, Gottlieb, & Fernandez, 2011; Michie et al., 2013). Poor intervention descriptions in research protocols and published study reports often preclude inferring which BCTs where delivered, why and how, which poses a major barrier to intervention replication, implementation and the conduct of informative systematic reviews (De Bruin, Viechtbauer, Hospers, Schaalma, & Kok, 2009; McCleary, Duncan, Stewart, & Francis, 2013). In the last decade, researchers have therefore paid considerable attention to improving the quality of intervention descriptions in randomised controlled trials (RCTs, Abraham, Johnson, De Bruin, & Luszczynska, 2014; Abraham & Michie, 2008; Albrecht, Archibald, Arseneau, & Scott, 2013; Boutron, Moher, Altman, Schulz, & Ravaud, 2008; Des Jarlais, Lyles, & Crepaz, 2004; Hoffmann et al., 2014; Michie et al., 2013; Zwarenstein et al., 2008). Considerably less attention has been paid, however, to improving descriptions of the support provided to control groups in behaviour change intervention trials, who typically received treatment-as-usual (TAU) or an augmented version thereof. (Burns, 2009; Burns et al., 2007; De Bruin et al., 2009; Freedland, Mohr, Davidson, & Schwartz, 2011; Löfholm, Brännström, Olsson, & Hansson, 2013; Wagner & Kanouse, 2003). Yet, systematic reviews and meta-analyses suggest that the active content of TAU can vary considerably between trials. Importantly, the quality of TAU can influence outcomes in control groups, and thus trial effect sizes (Ayling, Brierley, Johnson, Heller, & Eiser, 2015; Bishop, Fenge-Davies, Kirby, & Geraghty, 2015; De Bruin et al., 2009; De Bruin et al., 2010a).

Guidelines such as CONSORT, WIDER and TIDieR call for control group descriptions in equal detail as intervention content (Albrecht et al., 2013; Boutron et al., 2008; Hoffmann et al., 2014; Zwarenstein et al., 2008). However, no information is given on how to obtain these data, or summarise TAU data for reporting when it is collected from multiple sources (e.g. health care professionals and/or study sites). Consequently, study reports rarely include any detail about the active content of care provided to control groups (Ayling et al., 2015; De Bruin et al., 2009; De Bruin et al., 2010a; Freedland et al., 2011; Oberjé, De Kinderen, Evers, Van Woerkum, & De Bruin, 2013; Schoenwald et al., 2011), which can lead to inaccurate conclusions about intervention effectiveness and their most effective ingredients (De Bruin et al., 2009; De Bruin et al., 2010a).

Accurately describing the active content of behaviour change counselling in TAU can be challenging, especially in the context of RCTs with financial and time constraints. Several direct and indirect methods are available to explore the content of patient–clinician counselling (Erlen et al., 2014; Hrisos et al., 2009). Direct methods, such as video- or audio-taped observations, can provide accurate reflections of care content, but can be biased if both the patient and provider are aware of being observed (Peabody, Luck, Glassman, Dresselhaus, & Lee, 2000; Wilson & McDonald, 1994). Observing clinical interactions, as well as other direct methods such as unannounced 'standardised' or 'simulated' patients, can therefore be prone to measurement effects (Luck & Peabody, 2002; Van Zanten, Boulet, Norcini, & McKinley, 2004). Moreover, considerable resources are required for coding a representative number of consultations per clinician, and these costs rapidly escalate when many clinicians provide TAU to control group patients. Using direct methods to capture TAU provided to control groups may thus not be feasible in intervention research (Hrisos et al., 2009). Care content can also be investigated indirectly using proxy measures, such as closed-ended standard care checklists (De Bruin et al., 2009), or patient vignettes (Hughes & Huby, 2002). Despite

their low-response burden, indirect measures may overestimate the active content of care by promoting social desirability bias (Fisher, 1993; Peabody et al., 2004; Spies, Mokkink, De Vries Robbé, & Grol, 2004). Given the limitations of available methods, it may be useful to explore other options.

In this study, a semi-structured open-ended questionnaire was pilot-tested to assess the quality of usual medication adherence care delivered to control groups. The TAU open-ended questionnaire is an alternative for available methods, as it potentially explores TAU more feasibly (less time required and less costly to use) than direct methods, and more accurately than other indirect methods (no social desirability bias as the questions are minimally suggestive/cueing). The TAU open-ended questionnaire was used in a multicentre RCT examining the (cost-) effectiveness of the Adherence Improving self-Management Strategy (AIMS intervention) compared to TAU among HIV-infected patients using combination antiretroviral therapy (De Bruin, Hospers, Van den Borne, Kok, & Prins, 2005; De Bruin et al., 2010b, Oberjé et al., 2013). In the current study, four research questions were explored: (1) Is it feasible to use the TAU open-ended questionnaire in the context of a large RCT? (2) Are TAU descriptions sufficiently detailed to allow for BCT coding? (3) Can BCTs be reliably coded based on the TAU descriptions? (4) What is the variability between nurses and between clinics in the total number of BCTs reported?

Methods

Setting

Seven HIV-clinics in the Netherlands, with in total 21 HIV-nurses, participated in the AIMS-study: Academic Medical Centre, Amsterdam (7 nurses); Slotervaart Hospital, Amsterdam (3 nurses); St. Lucas-Andreas Hospital, Amsterdam (2 nurses); Leiden University Medical Centre, Leiden (2 nurses); HAGA Hospital, The Hague (2 nurses); Erasmus Medical Centre, Rotterdam (3 nurses); and Isala Clinic, Zwolle (2 nurses). The nurses were asked to fill in the paper-and-pencil version of the TAU open-ended questionnaire during a meeting prior to the start of the AIMS study.

TAU open-ended questionnaire

The TAU open-ended questionnaire contained semi-structured open-ended questions with free text for nurse responses. In order to increase the probability that all relevant elements of the TAU were reported, rather than using a single question (e.g. 'Please report all the things you do to support adherence among your patients') multiple questions were used as 'probes'. The content of these questions was guided by a previously developed HIV-treatment adherence taxonomy of BCTs; and by the results of a systematic review of HIV-treatment adherence trials that included TAU data collected from study authors using a standard care checklist (De Bruin et al., 2009; De Bruin et al., 2010a). The questions in the current open questionnaire reflect the broad categories in which adherence support is typically delivered: informing patients, motivating patients, goal setting, problem solving, and it makes a distinction between activities that are typically done during the start-up of a treatment (e.g. providing information and make a medication intake plan) and those that are more likely to be delivered during follow-up

sessions (e.g. identify adherence problems and solutions). Table 1 shows the open-ended questions used, and one additional question to enquire whether any adherence-related activities were delivered not covered by these questions. The questionnaire was distributed in Dutch. The original TAU open-ended questionnaire with instructions for respondents included is also available online as supplementary material.

The nurses were instructed (both verbally and in an introductory text) to report on the activities that they 'routinely deliver to the majority of their patients', rather than occasional activities to specific individual cases. The nurses were also instructed, both verbally and on paper, to describe each activity, strategy or method in as much detail as possible. For instance, they were instructed that 'motivational interviewing' would be too non-concrete, and that they had to describe concretely what activities they were performing to support adherence. The researchers were present during completion of the questionnaire to answer possible questions from the nurses.

Coding procedure

Two authors (EO and MdB) independently coded the adherence support activities reported by nurses. Disagreements were resolved in a consensus meeting. A coding manual was used to determine which standard care activities could be considered as BCTs. The questions and the coding manual were developed based on the same adherence-adapted BCT taxonomy. It includes 38 items that describe distinct adherence-enhancing BCTs. This 38-item adherence to medication taxonomy is an adapted version of the behaviour change taxonomy from intervention mapping (Bartholomew et al., 2011) and Abraham and Michie (2008). The taxonomy is available on the Open Science Framework (https://osf.io/zdi5q/). The coders included one additional BCT (a 39th) in

Table 1. The TAU open-questionnaire.

	Question	Domain of adherence counselling
#1	What information do you think patients need to receive regarding their medication and adherence? How do you present that information?	Informing
#2	Do you try to motivate patients to strictly adhere to their medication? If yes, how?	Motivating
#3	Do you develop a medication intake plan together with the patient? If yes, how do you do this? What topics do you usually address, and which adherence strategies do you routinely discuss?	Planning
#4	If patients suggest plans for how to take their medication intake, or how to solve problems, do you systematically pay attention to how goals are set? Please explain your answer (yes/no)?	Goal setting
#5	Based on your experience, what are the three most common reasons for not taking medication? Which strategies do you discuss with patients to manage these problems?	Problem solving
#6	During follow-up visits, do you evaluate adherence and potential adherence problems? If yes, how? If not, why not?	Any of the above but during follow-up visits
#7	Are there any important activities that you do to support medication adherence that we did not ask about?	Any of the above

the manual to capture the relevant adherence supporting activity 'reducing psychological barriers'. All coded BCTs were given one point each. BCTs that were reported both at treatment-initiation and for follow-up meetings were given two points.

Analyses

The analyses were performed in four steps. First, to assess feasibility of the TAU open-ended questionnaire, we examined time to complete the questionnaire, the amount of missing data and the extent to which nurses required help to complete the questionnaire. Second, to assess completeness and clarity of responses, we examined whether TAU descriptions were detailed enough to allow for BCT coding. The open-ended questions were compared to each other to assess whether some questions were more likely to yield ambiguous descriptions of TAU activities than others. Examples of descriptions with adequate and inadequate level of detail were given. Third, to assess whether BCTs were reliably coded, Cohen's kappa statistic was used to examine the intercoder reliability of each BCT. Fourth, to assess variability in TAU between nurses and between clinics, the total number of reported BCTs was computed.

Results

Participants

All nurses returned their questionnaire ($N = 21$). Their mean age was 44 years (SD = 8.46), 15 participants were female, and all nurses were Dutch. Two nurses had less than one year nursing experience and six nurses had more than 10 years nursing experience ($M = 7.81$, SD = 6.35). All nurses completed higher vocational nursing education and six nurses completed post-graduate education for 'Advanced Nursing Practitioner'. Nineteen nurses completed the (compulsory) three-day course 'Motivational Interviewing'. Most nurses reported that they participated in updates of 'Motivational Interviewing' or other courses not directly related to adherence support (e.g. counselling and health behaviour change).

Feasibility

The nurses were given 60 min to complete the adherence TAU open-ended questionnaire. All nurses finished well on time (range = 25–45 min) and responded to all questions. After being instructed about how to respond to the TAU open-questions, the nurses did not solicit any further help except for two nurses requesting clarification on one item (question #4). Apparently, the concept of thinking about how to formulate goals was new to these nurses. The responses to question #7, which was added to enquire whether nurses delivered any adherence-related activities that were not already covered by questions #1–6, were generally brief and produced very little additional relevant information.

Descriptions of TAU activities

A preliminary qualitative analysis of responses was conducted to assess completeness and clarity of responses. Most parts of the responses were sufficiently concrete, so that

BCTs could be easily identified. However, there were also sections of text where the coders had the impression that one or multiple BCTs might have been delivered, but the level of detail was insufficient to confidently code BCTs. These suboptimal TAU descriptions were also the main reason for disagreement between the coders, and seemed to occur more frequently with questions #1, #5 and #6; and more often with some nurses who tended to formulate their responses at a less concrete level.

An example of text that was unclear is 'we make a plan together and we evaluate the plan'. This suggests that the BCT 'review of general and/or specific goals' was delivered. However, the text could not be coded with confidence because it did not adequately fit the definition 'reconsideration of previously set goals or intentions following previous goal setting, and an attempt to act on those goals'. An example of text that was adequate to code as this BCT is 'we talk about the patient's daily activities and the agreed time of the day to take medication. In addition, we evaluate why this time of the day was chosen, and how it works for the patient. In case it does not work well, we look for alternatives'.

A second example of text that was unclear is 'I recommend several tools', which is likely to refer to tools such as an alarm device. This suggests that the BCT 'use of cues' was delivered but – again – the text could not be coded with confidence because it did not adequately fit the definition (i.e. 'teaching or stimulating the patient to identify environmental prompts that can be used to remind them of the behaviour and/or goal set'). An example of text that was adequate to code as this BCT is 'I advise the patient to use an alarm device on their mobile phone to remind themselves to take medication'.

A final example of text that was unclear is 'I discuss medication intake with the patient'. This suggests that the BCT 'self-report of behaviour' was delivered (note: 'self-report of behaviour' is an assessment technique, not an actual change technique). However, the text could not be coded with confidence because it did not adequately fit the definition 'assessment of own adherence behaviour through self-report'. An example of text that was adequate to code as this BCT is 'I ask how many times the patient skipped a dose or took medication too late, and why'.

Intercoder reliabilities

Intercoder reliabilities were examined for the identification of 38 BCTs. These are presented in Table 2, with the percentage of agreement for each BCT and by how many nurses the BCT was reported. In 13 of the 38 BCTs, both coders agreed that there were no instances of a BCT in any of the questionnaires. For three of the 38 BCTs, there was 100% agreement between coders judging that the BCT was present. For the remaining 22 BCTs, kappa scores ranged from .0 to 1.0 with a mean of .79 and a median value of .86 (SD = .26). Nineteen of the 22 tests (86%) produced a satisfactory kappa above .6, which is considered as substantial inter-coder reliability (Landis & Koch, 1977). Three tests produced a kappa below .6 (i.e. 'persuasive argument, belief selection', 'provide general information' and 'review of general and/or specific goals'). Across all 38 BCTs, agreement rates ranged from 71 to 100% with a mean value of 97% and a median value of 99% (SD = 5.96).

Table 2. Percentage agreement, kappa, and number of times each behaviour change technique was coded.

Determinant	BCT	% of Agreement	Cohen's kappa	Times coded as BCT[a]
Knowledge	Provide general information	100	N/A	21
	Increase memory and understanding	100	1.0	20
Awareness	Risk communication	95	.83	17
	Self-monitoring of behaviour	100	N/A	0
	Self-report of behaviour[b]	86	.64	15
	Electronic monitoring of behaviour[b]	100	N/A	0
	Reflective listening	100	1.0	1
	Delayed feedback of behaviour	100	N/A	0
	Direct feedback of behaviour	100	1.0	11
	Feedback of clinical outcomes	100	1.0	4
Social influence	Provide info about peer behaviour	100	N/A	0
	Social comparison peers	100	N/A	0
	Mobilise social norm	100	N/A	0
Attitude	Re-evaluation, self-evaluation	95	.77	2
	Persuasive communication	95	.00	21
	Reward behavioural progress	100	1.0	1
	Reward motivational progress	100	N/A	0
Self-efficacy	Modelling	100	1.0	1
	Verbal persuasion	95	.64	1
	Practice, guided practice	100	1.0	2
	Plan coping responses	95	.86	17
	Graded tasks, goal setting	95	.77	2
	Reattribution, external attribution	100	N/A	0
Intention	General intention formation	86	.32	3
	Develop medication intake schedule	100	N/A	21
	Specific goal setting	95	.90	10
	Review general and/or specific goals	71	.42	14
	Agree behavioural contract	100	N/A	0
Action control	Use of social support	91	.81	9
	Use of cues	95	.83	17
	Self-persuasion	100	N/A	0
Maintenance	Formulate goals for maintenance	100	N/A	0
	Relapse prevention	100	N/A	0
Facilitation	Provide materials	100	1.0	4
	Continuous professional support	86	.63	15
	Individualise regimen	95	.91	10
	Cope with side effects	95	.90	14
	Reduce environmental barriers	100	N/A	0
	Reduce psychological barriers	– [c]	– [c]	4

[a]The score was determined after the consensus meeting.
[b]An assessment technique, not an actual *change* technique.
[c]Percentage of agreement and Cohen's kappa not included here. This BCT was added after the coding procedure.

Variability in BCTs

Table 3 shows the set of BCTs reported by the 21 nurses involved in the AIMS study, after coders reached agreement. Three BCTs were reported by all nurses (i.e. 'provide general information', 'persuasive argument, belief selection' and 'develop medication

Table 3. The set of BCTs reported by the 21 nurses involved in the AIMS-study[a].

BCT	#[b]1	#2	#3	#4	#5	#6	#7	#8	#9	#10	#11	#12	#13	#14	#15	#16	#17	#18	#19	#20	#21	Times coded as BCT[c]
Provide general information	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	21
Increase memory and understanding	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	20
Risk communication	✓	✓	✓	×	✓	✓	×	×	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	✓	17
Self-report of behaviour[d]	×	✓	✓	✓	✓	×	✓	✓	×	✓	✓	✓	✓	✓	×	✓	✓	×	✓	✓	×	15
Reflective listening	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	✓	×	×	×	1
Direct feedback of behaviour	×	✓	×	×	✓	✓	✓	×	✓	×	×	×	✓	✓	✓	✓	×	✓	✓	×	×	11
Feedback of clinical outcomes	×	×	×	×	×	✓	×	✓	×	×	×	✓	✓	×	×	×	×	×	×	×	×	4
Re-evaluation, self-evaluation	×	×	×	×	×	×	×	×	×	×	×	×	×	✓	×	×	✓	×	×	×	×	2
Persuasive communication	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	21
Reward behavioural progress	×	×	×	×	×	×	×	✓	×	×	×	×	×	×	×	×	×	×	×	×	×	1
Modelling	×	×	×	×	×	×	×	×	×	×	×	×	×	✓	×	×	×	×	×	×	×	1
Verbal persuasion	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	✓	×	×	1
Practice, guided practice	×	×	×	×	×	✓	×	×	×	×	✓	×	×	×	×	×	×	×	×	×	×	2
Plan coping responses	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	×	✓	✓	✓	×	✓	×	17
Graded tasks, goal setting	×	×	×	✓	×	✓	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	2
General intention formation	×	×	×	×	×	×	✓	×	×	×	×	×	✓	×	×	✓	×	×	×	×	×	3
Develop medication intake schedule	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	21
Specific goal setting	×	✓	✓	×	×	×	✓	✓	✓	✓	×	✓	×	×	✓	✓	×	✓	×	×	×	10

Review general and/ or specific goals	×	×	✓	×	✓	✓	✓	✓	×	✓	✓	✓	✓	×	✓	✓	×	✓	✓	✓	×	14
Use of social support	✓	×	×	×	✓	×	×	✓	×	✓	✓	×	×	×	✓	✓	✓	✓	×	×	×	9
Use of cues	×	✓	✓	×	✓	×	✓	×	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	17
Provide materials	×	×	×	×	×	×	×	×	×	×	×	×	✓	✓	×	✓	×	×	✓	×	×	4
Continuous professional support	×	✓	✓	×	✓	✓	×	✓	✓	✓	×	✓	✓	✓	✓	×	×	✓	✓	✓	✓	15
Individualise regimen	×	×	✓	×	✓	×	✓	✓	×	×	✓	×	✓	✓	✓	×	×	✓	×	✓	×	10
Cope with side effects	✓	✓	✓	✓	✓	✓	×	✓	✓	×	×	×	✓	×	✓	✓	×	✓	✓	✓	×	14
Reduce psychological barriers	×	×	×	×	×	×	×	×	×	×	✓	✓	✓	×	×	×	×	×	✓	×	×	4

Note: × = The BCT was not identified; ✓ = The BCT was identified.
[a]BCTs which were not reported by any nurse are omitted in this table.
[b]The nurses are numbered to ensure anonymity.
[c]The score was determined after the consensus meeting.
[d]An assessment technique, not an actual *change* technique.

intake schedule'). None of the nurses reported any BCT addressed at the determinants 'social influence' (i.e. 'provide information about peer behaviour', 'provide opportunities for social comparison' and 'mobilise social norm') and 'maintenance' (i.e. 'formulate goals for maintenance of behaviour' and 'relapse prevention'). The total number of BCTs reported on nurse level ranged from 7 to 19 BCTs ($M = 13.86$, SD = 3.35). The average number of BCTs in the seven clinics involved in the AIMS study ranged from 9.67 to 16.50 BCTs ($M = 14.00$, SD = 2.62). The number of BCTs reported was unrelated to age ($r = -.06$, 95% CI [−.41, .32]) and the years of nursing experience ($r = .28$, 95% CI [−.15, .62]). The results from the independent sample t tests indicated that male nurses ($M = 13.50$, SD = 3.88, $N = 6$) reported an equal number of BCTs compared to female nurses ($M = 14.00$, SD = 3.25, $N = 15$), $t(19) = -.30$, $p = .76$, two tailed, 95% CI [−3.97, 2.97]. Nurses who completed post-graduate education ($M = 14.40$, SD = 3.42, $N = 6$) reported also an equal number of BCTs compared to those who did not complete post-graduate education ($M = 12.50$, SD = 3.02, $N = 15$), $t(19) = 1.19$, $p = .25$, two tailed, 95% CI [−1.45, 5.25].

Discussion

Although CONSORT, WIDER and TIDieR statements call for control group descriptions in equal detail as intervention content (Albrecht et al., 2013; Boutron et al., 2008; Hoffmann et al., 2014; Zwarenstein et al., 2008), no guidance is given on how to obtain these data. The objective of this study was to pilot-test an open-ended questionnaire to reliably assess BCTs delivered by HIV-nurses as part of their routinely delivered adherence support. The results suggest that using the TAU open-ended questionnaire is feasible (i.e. nurses understood the questions and the questionnaire could be completed in a reasonable amount of time) and that most of the responses could be reliably coded with a BCT taxonomy. The results are also potentially relevant for interpreting the effects of this trial, which evaluates the (cost-) effectiveness of the AIMS intervention (De Bruin et al., 2005; De Bruin et al., 2010b, Oberjé et al., 2013), given the variability between nurses and clinics in the number and type of BCTs delivered. This study suggests therefore that using a semi-structured open-ended questionnaire with the right instructions and the right prompts can be an appropriate method for assessing the active content of TAU, and thus improve trial reports and meta-analyses.

Twenty-six BCTs were identified from TAU descriptions of 21 nurses, 23 of which had kappa scores of .60 or above. Three BCTs scored lower than .60. Both coders agreed that some of the nurse responses were insufficiently detailed to allow for confident BCT coding, which was also a reason for low agreement rates and low kappa scores. Researchers who intend to use this method in their trials may consider several options for improvement, such as improving the instructions to respondents to ensure an adequate level of detail of responses; or immediate coding of the completed questionnaires and asking for clarification of nurse responses when they are too general.

Recent meta-analyses examined the variability and impact of TAU provided to control groups in RCTs evaluating HIV-treatment adherence interventions (De Bruin et al., 2009; De Bruin et al., 2010a). De Bruin and colleagues assessed TAU using a checklist that was completed by study authors, and found that *TAU capacity scores* (i.e. a sum-score of the number of TAU BCTs delivered in each study, weighed for tailoring and

repetition of BCT delivery) can vary considerably between studies, impact control group outcomes and consequently trial effect sizes. The results from the current study suggest that the active content of TAU within one multicentre RCT can vary substantially, despite that nurses have the same guidelines, follow the same courses and so forth. This variance may be explained by factors such as the degree to which the management thinks providing adherence support is a priority and the amount of training received, nursing experience, or the quality and amount of training nurses received (Blegen, Vaughn, & Goode, 2001; Kane, Shamliyan, Mueller, Duval, & Wilt, 2007). This also raises the question of how this TAU variability can be taken into account in the analysis of this trial, and in future meta-analyses of behaviour change interventions that aim to control for variability in TAU in order to arrive at more accurate estimates of intervention effects, and the most effective BCTs. To facilitate the use of these data in such analyses, we recommend that reports of behaviour change interventions include (either in the manuscript or as an appendix) a table detailing for each TAU provider which BCTs had been coded (similar to Table 3 in this manuscript).

This study also has some limitations. First, despite that the questions are minimally directive, the nurse responses might not accurately represent TAU. Examining convergent validity (e.g. by comparing questionnaire responses with coded video or audio observations) and predictive validity (e.g. by comparing TAU scores with adherence and/or clinical outcomes) would be important steps for future research. Second, we did not have the opportunity to repeat the same measurement procedure – under the same conditions – within a short period of time. We were therefore unable to examine test-retest reliability.

Results from the TAU open-ended questionnaire can also have practical implications that go beyond improving the reporting of the care provided to control groups. By examining the relationship between the active content of TAU and patient outcomes, such as adherence and plasma viral load, the most effective (combinations of) BCTs can be identified for supporting adherence. Results from such studies – if sufficiently rigorously conducted – can be informative for in HIV-nurses' training programmes to improve the effectiveness of their TAU.

To conclude, the current study makes primarily a methodological contribution to improved reporting of the active content of care provided to control groups in trials evaluating behaviour change interventions. The TAU open-ended questionnaire demonstrates good feasibility to collect data at the level that can be reliably coded with a taxonomy of BCTs. Further validation of data collected in this way would strengthen confidence in the accuracy of these data, and lead to improved trial reports and analyses, and evidence syntheses.

Competing interest

All authors declare that they have no competing interests.

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Supplemental data

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