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Published in:
British Journal of Health Psychology

DOI:
10.1111/bjhp.12668

Publication date:
2023

Document version:
Final published version

Received: 24 November 2022 | Accepted: 27 April 2023

DOI: 10.1111/bjhp.12668

the british psychological society
promoting excellence in psychology

ARTICLE

The GLA:D BACK self-management adherence and competence checklist (SMAC Checklist)—Development, content validity and feasibility

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Funding information
Danske Fysioterapeuter

Abstract

Objectives: To unpack the complexity and impact of self-management interventions targeting musculoskeletal health conditions, we need to learn more about treatment delivery in clinical settings. Fidelity evaluation can illuminate how complex treatments are delivered and help understand the elements that lead to the effect. The objective of this study was to develop a checklist for the evaluation of the clinicians' delivery of structured patient education and exercise intervention for people with persistent back pain, the GLA:D Back intervention. The intent was to provide a checklist adaptable for the general delivery of self-management interventions for musculoskeletal pain.

Methods: We derived items for the treatment delivery fidelity checklist from behaviour change techniques and theory about communication style. We applied a three-step developmental process covering *developing a preliminary fidelity intervention framework*, *validating checklist content* and *piloting and refining the checklist*.

Results: We developed the adaptable fidelity checklist, The GLA:D BACK Self-management Adherence and Competence Checklist (SMAC Checklist). Evaluation of clinical practice using the checklist was feasible and acceptable by clinicians. Preliminary results indicate satisfactory observer agreement during pilot testing of the checklist.

Conclusion: The GLA:D BACK Self-management Adherence and Competence Checklist is a fidelity measurement tool for the assessment of the delivery of a self-management supportive intervention for people with

persistent back pain. The intention is that it can be useful as an adaptable tool for use across self-management interventions for musculoskeletal pain.

KEYWORDS

back pain, exercise therapy, delivery of health care, health care quality, patient education, self-management, fidelity of delivery

Statement of contribution

What is already known on the subject?

- Interventions designed to support self-management are challenging to deliver.
- No generic measurement tools targeted treatment delivery within self-management supportive back care exist.
- Evaluation of treatment delivery is necessary to understand which components are particularly difficult for clinicians to deliver and to understand how delivery affects patient outcomes.

What does this study add?

- We developed the GLA:D BACK Self-management Adherence and Competence Checklist targeted adherence and competence of a self-management supportive group-based intervention entailing patient education and exercises.
- The checklist covers commonly targeted behaviour change elements and can easily be adapted to similar complex health interventions.

BACKGROUND

Most people with musculoskeletal health conditions are managed in primary care; however, care varies widely across clinician types and settings. Thus, deeper insights into how care is delivered and whether clinicians deliver interventions in a way that is consistent with clinical guidelines and how care was intended are needed.

Treatment fidelity refers to the extent to which an intervention is delivered faithfully to how it was planned (Borrelli, 2011; Breitenstein et al., 2010; Hodder et al., 2016). Borrelli et al. described treatment fidelity in five domains including, *study design, provider training, treatment delivery, treatment receipt* and *treatment enactment*. *Treatment delivery* is the most frequently assessed domain within fidelity research and involves treatment differentiation (the delivery of target treatment within each treatment arm), treatment competency (the provider's skills) and treatment adherence (treatment components delivered as intended; Slaughter et al., 2015; Walton et al., 2017). Assessment of treatment fidelity is important in clinical trials to ensure that estimated effects are truly effects of the described intervention (Borrelli, 2011). Also, it is relevant to identify factors influencing the implementation of interventions in clinical practice (Hodder et al., 2016).

Musculoskeletal pain-related conditions are among the most common reasons why people seek care (Vos et al., 2016). These are often complex health problems, influenced by a complicated interaction of biological, social, cultural and psychological factors. Management therefore invariably involves multifaceted interventions including patient education, supervised exercise therapy and strategies to support self-management (Hartvigsen et al., 2018). Such interventions can be challenging to deliver because

they are highly dependent on the clinician–patient interaction (Cowell et al., 2021, 2018; Hafliðadóttir et al., 2021; Synnott et al., 2015). Still, little is known about exactly how they are delivered (Cowell et al., 2021), or if and how fidelity to treatment delivery may affect outcomes (Hodder et al., 2016; Lee et al., 2016). Therefore, there is among other things, a need to develop valid tools to measure fidelity in the delivery of complex interventions (Ginsburg et al., 2021; Walton et al., 2017; Walton, Spector, Roberts, et al., 2020).

To study treatment delivery of complex interventions and how delivery impacts patient outcomes, the content of these interventions needs deciphering. Treatment delivery may be simple to define with pharmacological treatments because the content is well-described and easy to define. It is more challenging with complex behaviour change interventions consisting of multiple components where intended delivery may not be straightforward to define (Galea Holmes et al., 2022; Ginsburg et al., 2021; Hodder et al., 2016; Mansell et al., 2016; Walton et al., 2017). Still, it is possible to evaluate such interventions through the assessment of behaviour change techniques (BCT) and communication styles used in patient–clinician interactions. BCTs are strategies to facilitate behaviour change, for instance, goal setting, feedback on behaviour and action planning. They are operationalized in a comprehensive BCT taxonomy (Michie et al., 2015) that has shown useful for decomposing interventions into active elements and for evaluating treatment fidelity in clinical trials (Beck et al., 2016; Keogh, Matthews, & Hurley, 2018; Tate et al., 2016; Toomey et al., 2020). Furthermore, clinicians' communication can be evaluated by assessing components of specific communication techniques/styles (Galea Holmes et al., 2022; Murray et al., 2015, 2018).

In Denmark, the GLA:D Back programme aims to implement recommendations from clinical guidelines for managing low back pain (LBP; Kongsted, Ris, et al., 2019a). It is a treatment option for patients with persistent or recurrent LBP (Kongsted, Ris, et al., 2019b) aiming to help patients improve self-management of LBP through a structured group-based programme of patient education integrated with supervised exercises. Clinicians are trained in delivering this intervention and provided with materials to support this (Kongsted, Hartvigsen, et al., 2019).

The GLA:D Back programme exemplifies the need for studying the fidelity of clinicians' delivery of structured intervention programmes. GLA:D Back has shown feasible to implement in various settings (Fernandez et al., 2022; Kongsted, Ris, et al., 2019b; Lemieux et al., 2021). However, implementation is not straightforward. Some clinicians do not buy in on the underlying cognitive-behavioural principles, and some of those who do, find it challenging to deliver (Ris et al., 2023). Also, the patient receipt indicates potential challenges in targeting individual needs (Joern et al., 2022). Patients are generally satisfied with the intervention and have high adherence to the programme (Ris et al., 2021), but it is perceived differently by patients depending on how messages and communications resonate with the individual's experiences and beliefs about LBP (Joern et al., 2022).

As the GLA:D Back intervention was designed to operationalize recommendations from clinical guidelines to use active interventions and support self-management while focusing on general cognitive and behavioural aspects of musculoskeletal pain, the approach to fidelity assessment in the GLA:D Back programme will be adaptable for similar interventions across musculoskeletal pain conditions (Kjaer et al., 2018).

This study aimed to develop and content validate a checklist for the evaluation of clinicians' adherence and competence in the delivery of the main elements of the GLA:D Back intervention, which can be adapted for other self-management interventions.

METHOD

We developed a treatment delivery fidelity checklist in a process that resembled a newly published five-phases model for developing fidelity measures for complex health interventions (Walton, Spector, Williamson, et al., 2020): (1) *reviewing previous measures*, (2) *analysing intervention components and developing a framework outlining the content of the intervention*, (3) *developing fidelity checklists and coding guidelines*, (4) o*btaining*

feedback about the content and wording of checklists and guidelines, and (5) *piloting and refining checklists and coding guidelines to assess and improve reliability* (Walton, Spector, Williamson, et al., 2020). The method used followed three steps: Step one covers phases one and two, step two comprised phase three and four, and step three include phase five (Figure 1).

Development of a preliminary fidelity intervention framework (Step 1)

Conceptualizing competence in the delivery of GLA:D Back (Step 1 A)

We chose an approach comparable to the SOLAS (self-management of osteoarthritis and LBP through activity and skills) project, which had a similar theoretical underpinning to GLA:D Back (Keogh, Matthews, & Hurley, 2018). In SOLAS, fidelity assessment incorporated an assessment of delivered BCT with the principles from Borrelli's treatment fidelity framework (Borrelli, 2011; Keogh, Matthews, & Hurley, 2018).

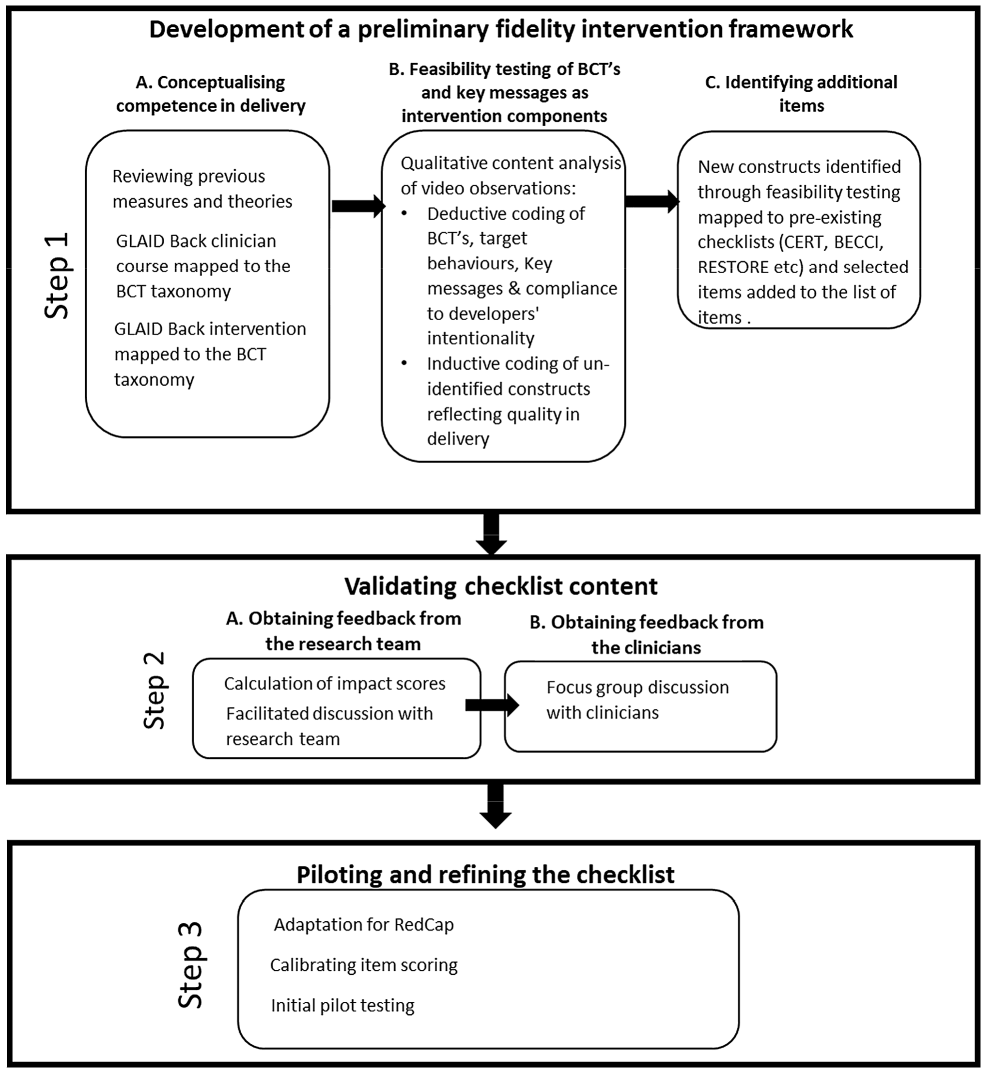

FIGURE 1 Process overview of the development of the checklist.

First, we listed the theoretical active elements of the intervention to define the *competent delivery* of GLA:D Back. We identified these elements by linking the GLA:D Back intervention description (Kjaer et al., 2018) as well as a GLA:D Back clinician course (Kongsted, Ris, et al., 2019a) to the BCT taxonomy following the principles for coding BCTs (The UCL Centre for Behaviour Change, 2020). Also, the delivery of eight key messages in the GLA:D Back programme was listed as elements of *competence* (Kjaer et al., 2018).

Feasibility testing of BCTs and key messages as intervention components (Step 1 B)

To assess whether the elements of *competence* could be identified by observation, a research assistant conducted a qualitative content analysis (Elo & Kyngäs, 2008) of transcribed soundtracks from video observations of three clinicians delivering a total of six sessions of GLA:D Back (3 hr of patient education and 3 hr of exercise sessions). The coding list used in the deductive part of the qualitative content analysis was based on elements of *competence* identified during the process of conceptualizing (Figure 1; Step 1A). In detail, the coding list contained codes for, the delivery of BCTs, the corresponding target behaviours (knowledge, physical skills and cognitive skills), GLA:D Back key messages, and codes addressing *intentionality* (the compliance to the intervention developers' basic principles for delivering GLA:D Back).

Identifying additional items (Step 1 C)

In addition to the deductive coding during the content analysis, we inductively coded the video recordings, which revealed additional constructs of importance to the competent delivery of GLA:D Back (Thomas & Harden, 2008). We identified three themes during the inductive coding: *building rapport, self-management supportive guidance and building a framework of shared knowledge*. These themes matched items from existing checklists: Restore Clinician Competency Checklist (Kent et al., 2019), the Group Facilitation Competency Checklist (Wong et al., 2019), the Communication Evaluation in Rehabilitation Tool (CERT; Murray et al., 2018), and The Behaviour Change Counselling Index (BECCI; Beck et al., 2016).

Step 1 resulted in a draft of a *preliminary fidelity intervention framework* comprising a gross list of BCTs, key messages and items from the existing checklist matching the themes identified inductively (Appendix 1).

Validating checklist content (Step 2)

Content validity of item selection and wording was achieved by first performing a quantitative evaluation with input from six members of the GLA:D Back research team, followed by a qualitative part consisting of a focus group discussion with clinicians experienced in delivering the intervention.

Obtaining feedback from the research team (Step 2 A)

The GLA:D Back research team all took part in the development of the GLA:D Back programme and consisted of six Danish researchers with varying professional backgrounds (two chiropractors, three physiotherapists and one psychologist) and a broad continuum of research experience within musculoskeletal health ranging from Research Assistant to Professors.

For each item in the preliminary fidelity framework, the GLA:D Back research team individually stated whether a specific item should be present in the final checklist (yes or no) and rated the importance of the item on a 5-point scale ranging from 'not very important to 'extremely important for delivering GLA:D Back.

An impact score was then calculated by multiplying the proportion of participants nominating the item to be included in the final checklist with the average importance rating of the item (range

0–5; Juniper et al., 1992; Lemieux et al., 2021). Items with an impact score above 2.5 defined the first version of the checklist. The cut point was defined by the authors to keep the checklist as short as possible without missing important elements. To ease the interpretation in a GLA:D Back context, we translated the wordings from English to Danish language and accompanied each item with supplementary definitions and GLA:D Back specific examples. Next, the research team made pragmatic decisions through consensus discussions about further item reduction, the wording of items and other amendments. Finally, the addition of two global assessment items targeted *overall quality in delivery* and *overall fidelity in delivery to the GLA:D Back principles* was included to inform future clinimetric testing.

Obtaining feedback from the clinicians (Step 2 B)

The clinician's perspectives on competence in the delivery of GLA:D Back and their acceptability of being evaluated in clinical practice were assessed through a focus group discussion with six clinicians ($n = 15$ invited per e-mail) all experienced in delivering the GLA:D Back programme. Similar to the feasibility testing in step 1B, the methodological approach was inspired by a qualitative content analysis (Elo & Kyngäs, 2008). The first author established the contact with the participants and knew half of the participants from previous professional contact. The selection of informants by purposeful sampling ensured diversity in age, sex, years of experience, type of clinic and profession (Palinkas et al., 2015).

The first author (Msc PT), who was not part of the GLA:D Back developing or research team, moderated the focus group discussion which took place at the University of Southern Denmark and lasted for one and a half hours. A research assistant (Msc PT) ensured audio recordings during the meeting and made notes of non-verbal communication. Both moderator and assistant had some experience with qualitative research from previous projects.

A semi-structured interview guide facilitated the focus group discussion by presenting 10 statements about *competence* in the delivery of the GLA:D Back programme, and evaluation of clinical practice to facilitate group discussion.

BDH deductively coded transcripts of the audio recordings using the computer software for qualitative analysis ATLAS.ti (ATLAS.ti, 2023) looking for content related to the evaluation of treatment delivery based on the concepts of *acceptability*, *feasibility*, *applicability* and *competence in delivery* (De Vet et al., 2011). Quotations reflecting similar constructs formed themes that were subsequently mapped to the checklist, and additional items constructed from the themes were added to it. Transcripts or findings were not returned to the participants for review.

Piloting and refining the checklist (Step 3)

For the pilot testing, we created an electronic version using the REDCap software (Syddansk universitet, 2020). A coding instruction and definitions with illustrative examples for each item constituted the coding guideline.

Video recordings used in step 1b were used to evaluate the feasibility of the checklist and the coding guideline and to pre-assess interobserver agreement.

To calibrate the interpretations of interactions in the video observations, a research assistant and three of the programme developers first discussed observations of clinician–patient interactions in one video-recorded group-based exercise session. Next, two observers individually used the checklist to assess fidelity in delivery by registering if the checklist items were delivered or not at any clinician-patient interactions during one session. If delivered the quality of the delivery was evaluated using a 5-point ordinal scale indicating if delivery was according to the principles of GLA:D Back (+, ++) or in conflict with these (−, −−). If an item was delivered both in accordance and in conflict with GLA:D Back in the same session, it was scored +/−. Consensus discussions of coding

for each session led to amendments to the coding guidelines and reformulating items before moving on to coding the next sessions. Following the coding of sessions 5 and 6, the comparison of coding only led to minor amendments.

Preliminary observer agreement was evaluated as a precursor for reliability study by comparing the coding between the two observers across the entire checklist for all items with similar response options (two, three or five response options) while considering chance agreement by use of Cohen's Kappa (Cohen, 1968). For items with five response options, linear weights were applied to account for the ordinal nature of data and partial agreements (Gwet, 2014).

RESULTS

A fidelity checklist was developed for the GLAD back programme with the possibility of adapting it to other musculoskeletal conditions or pain disorders (Appendix 1). Items included in the final checklist with their origin and response options are presented in Table 1.

Development of a preliminary fidelity intervention framework (Step 1)

The preliminary fidelity framework consisted of 22 BCTs, 9 GLA:D Back specific key messages, and 17 items related to interpersonal skills (Appendix 1).

Validating checklist content (Step 2)

Assessment by the research team

The impact score of the items in the preliminary fidelity framework ranged from 1.2 to 4.8 points with 39 items above the cut-off at 2.5. From these, five items were removed because they either did not reflect a core element of the GLA:D Back programme, or the item could not be evaluated during the group sessions *(BCT 1.1 Goalsetting)*. For example, the BCT 'Goal Setting' was removed because goals are established in the initial individual session in GLA:D Back while reviewing the goal was considered relevant during group-based sessions (Appendix 2).

Also, eight items were removed because of overlap with other items and three items addressing unwanted clinician behaviour were added *(Providing mixed messages*, *Clinician acting paternalistic* and *Clinician disregarding or inattentive towards patients' emotional distress or pain)*. An *adherence* dimension reflecting fidelity to the basic structure of the GLA:D Back program *(item no. 8-18)* was added after step 2A. To capture the construct *intentionality*, we added a detailed scoring option for items in the competence dimension allowing us to score the alignment of delivery with the original principles of the GLA:D Back programme developers beyond delivery in terms of 'yes/no/not relevant'.

Assessment by clinicians

The clinicians demonstrated positive views on fidelity assessment in clinical practice, for instance by saying:

> "It promotes the improvement of the individual's competencies," "Contributes to knowledge about the effect of what we do in everyday life," "It is beneficial for patients" and "It is important."

The group discussions supported the inclusion of all selected items and led to adding two items within the adherence dimension *(The clinician being physically present)* and *(The clinician being GLA:D Back certified)*.

TABLE 1 Item overview.

Dimension	Item no. & name	Definition/example/comment	Origin	Response options
Basic information	Time and place of observation			Text + numeric
	Time of observation:		Desc	
	Name of the clinic:		Desc	
	Clinic postal code		Desc	
	How many clinicians were delivering the session?		Desc	
	The session and participants observed		Desc	
	Is there a form filled out for each clinician?		Desc	
	What session was observed?		Desc	
	How many patients participated in the session?		Desc	
	The number of cancellations?		Desc	
	The number of no-shows?		Desc	
	How many minutes did the session last?		Desc	
	Any comments on session duration?		Desc	
Adherence	Did the clinician adhere to the GLA:D Back the model?			Yes/No/Not Relevant
	The clinician is physically present during the session	*The clinician only leaves the room briefly and does not perform other tasks in parallel with the session*	FC	
	The clinician is GLA:D Back certified		FC	
	All participants received individual guidance during the session		FR2	
	The clinician facilitated group discussions during the session	*For example, ask the group "any successes or challenges since last time that you want to share?"*	FR2	
	Did the session begin with a group gathering? (Only relevant for training sessions)		FR2	
	Were any deviations from the basic structure of the GLA:D Program?	(Both orders, number of sessions, and session types must be correct.)	FR2	
	Describe deviations		FR2	
	Were GLA:D Back materials used?			Yes/No/Not Relevant
	The clinician refers to posters		FR2	
	The clinician uses the provided slides		FR2	
	The clinician uses laminated sheets with educational messages		FR2	
	The clinician refers to the content in the training folder		FR2	
	The clinician uses reflection exercises, e.g., "pain volume knob" or "resource balance model"	(Not applicable to exercise sessions)	FR2	

(Continues)

TABLE 1 (Continued)

Dimension	Item no. & name	Definition/example/ comment	Origin	Response options
Competence	Behaviour change techniques			Yes/No/Not Relevant + 5-point subscale
	Problem-solving - the clinician facilitates that the participant finds solutions to a specific problem	*Helps the participant explore alternative strategies for difficult/painful movements*	E-COMP	
	The clinician facilitates the evaluation of the participant's goal *setting*	*The clinicians ask about the participant's personal goals, e.g., how it is going with taking the stairs instead of the elevator*	E-COMP	
	The clinician provides *personal support*, guidance, or counselling, including cognitive behavioural therapy techniques, reflective questioning techniques, and motivational interviewing	*The clinician uses a reflective questioning technique to facilitate learning about outcomes of behaviour change e.g., "You told me that you have been in less pain the last few weeks, why do you think that is?"*	E-COMP	
	The clinician instructs the patient on how a particular behaviour is performed	*The clinician tells the patient how to do abdominal exercises", or "the clinician instructs the patient on the principles of progression of exercises"*	E-COMP	
	The clinician encourages participants to *experiment with behaviour*, including performing exercises in different ways	*"How would it feel if you round or twist more in the back during that exercise?"*	E-COMP	
	The clinician facilitates that the participants *compare their behaviours* with the behaviour of others.	*Draws the participants' attention to how a participant sits and stands or asks a participant to talk about how he gets breaks in his work*	E-COMP	
	The clinician *praises and acknowledges* the behaviour of the participant or participants verbally	*The clinician tells the participant that they do well in training. The clinician praises that the participant has cycled to work and taken the stairs*	E-COMP	
	The clinician facilitates *the reduction of negative feelings*, such as stress symptoms, pain, and anxiety about movement	*The clinician does relaxation exercises to reduce stress symptoms or address the participant's concerns directly*	E-COMP	
	The clinician facilitates *reframing* in terms of new angles, perspectives, and insights concerning a specific situation or problem	*The clinician focuses on the participant's values. The clinician explores patient experiences and asks for insights related to the participant's thoughts about pain*	E-COMP	

TABLE 1 (Continued)

Dimension	Item no. & name	Definition/example/comment	Origin	Response options
	The clinician uses *verbal persuasion* to support beliefs in participants' abilities in terms of mastery of back problems	*The clinician tells the participant that the back is strong and that they can get in good physical shape even if they have back pain*	E-COMP	
	The clinician *teaches knowledge* related to back pain	*The clinician talks about the prospect of back ailments and explains the concept of "benign back pain"*	E-COMP	
	Key messages			Yes/No/Not Relevant + 5-point subscale
	"The brain can turn pain up and down"		E-COMP	
	"Pain = alarm, not harm"		E-COMP	
	"(Natural) movement inhibits pain"		E-COMP	
	"Balance between capacity and demands"		E-COMP	
	"The back is strong"		E-COMP	
	"Bad posture is common"		E-COMP	
	"Action comes before improvement"		E-COMP	
	"The spine is made for movement"		E-COMP	
	Communication style			Yes/No/Not Relevant + 5-point subscale
	The clinician facilitates that the participants make decisions about their behaviour based on the participant's preferences and values	*"What types of activity do you like to do?"; "Now you've mentioned 3 different types. Are the 3 mentioned activities of equal importance to you?"*	IC+C	
	The clinician uses formulations that support the patient in self-determination, rather than dictating language	*"You know what's best for you in that particular situation"*	IC+C	
	The clinician appears as a credible source and seems confident in the dissemination of knowledge	*"Research shows that…" "it is my experience, that…"*	IC+C	
	The clinician reassures the participants	*"You can be completely safe, your back can tolerate that exercise"; "relapse with worsening pain is quite normal", and "exercise soreness is a natural response when starting a new form of training". "Keep in mind that pain acts as an alarm that may have become extra sensitive over time"*	IC+C	

(Continues)

TABLE 1 (Continued)

Dimension	Item no. & name	Definition/example/comment	Origin	Response options
	The clinician listens to the participants and leaves room for the participants to talk	*"Tell me more about what more about what happened yesterday when you had pain…"*	IC+C	
	The clinician employs an easily understandable everyday language	*"Have you guys had any good days since we were here last?"*	IC+C	
	The clinician asks about the participants' thoughts and emotions	*"What do you think about the fact that you don't have back pain at all anymore/ about the pain you're getting now?" "… how does it make you feel?"*	IC+C	
	Unwanted behaviour			Yes/No
	The clinician gives contradictory information to the participants	*"The back is a strong structure" - "you shouldn't turn and bend simultaneously" or the clinician says at one point that back pain is complex and does not reflect tissue damage, but subsequently says that "it's your discs that are worn out"*	IC+C	
	The clinician appears paternalistic and/or controlling	*e.g., "You must do these exercises at least 4 times a week". "Don't bend over that way, it might harm your back"*	IC+C	
	The clinician rejects or is inattentive to people with pain/anxiety	*A participant says that he gets pain during a specific exercise, but the clinician ignores the information and moves on to talk about something else*	IC+C	
	Overall rating			5-point agreement scale
	The observed session is delivered following the GLA:D Back principles.		FR2	
	The observed session is delivered with good quality?		FR2	
	Additional comments on the observed practice?		FR2	

Note: Desc: Descriptive items added to the electronic version by developers; E-COMP: Essential intervention component from intervention description; FC: Feedback from clinicians; FR2: Feedback Research team meeting no. 2; IC + C: Themes from inductive coding mapped to existing checklists [Restore clinician competency checklist (Kent et al., 2019; Ris et al., 2021), the Group Facilitation Competency Checklist (Thomas & Harden, 2008), the CERT (Kent et al., 2019) and The BECCI (Wong et al., 2019)].

Piloting and refining the checklist (Step 3)

Using the checklist was considered easy and intuitive and it took approximately 1½ hr to score a video recording of 1 hr.

Items that were challenging to agree on were: *Problem-solving*, *Social support unspecified*, *Autonomy supportive communication* and *Joint decision-making*, and minor amendments of wordings and examples for these were made to ease the scoring.

In the last of six observer agreement evaluations, the observed agreement was 79%, 83% and 75% for items with five, three and two response options, respectively. Kappa values were .7 for three response options and .4 for five response options (weighted), while kappa for unwanted behaviour with two response options was .4 across all six observations.

Uncertainty about the differentiation between + and ++ (or – and ––) based on the level of quality led to a consensus to use + or ++ to indicate the consistency of delivering an item, that is the specific item was delivered repeatedly aligned with the program's intentions. All amendments related to completing the checklist were added to the coding guideline.

DISCUSSION

We developed the SMAC Checklist assessment tool evaluating the delivery of a self-management-supporting intervention. The SMAC Checklist covers the dimensions of *adherence* to the program and clinicians' *competence* in treatment delivery. The competence dimension reflects the delivery of BCTs, the delivery of educational key messages, and the use of a self-management supportive communication style. Content validity was established by clinicians and researchers and the checklist was found feasible to use with the initial judgement of agreement between two observers showing good promise for the reliability of the checklist.

The checklist was developed for fidelity assessments in the GLA:D Back programme, but due to the integration of BCT's and items reflecting autonomy supporting communication style, especially the competence dimension is generic to self-management supportive care and adaptable for other interventions fostering behaviour change and self-management.

The SMAC Checklist captures elements that have been identified in previous studies (French et al., 2019; Keogh, Matthews, & Hurley, 2018; Mars et al., 2013). It is the first content-validated theory and guideline-based observational checklist, that is easily adaptable to similar self-management supportive group-based programmes targeted to patients with persistent musculoskeletal pain or potentially other chronic conditions.

In contrast to most fidelity assessment tools developed for clinical trials, the SMAC Checklist was developed for the evaluation of the routine delivery of structured care in clinical practice. To identify the challenges that clinicians face, there is a need for practice-based investigations of the delivery of complex interventions. Clinicians managing musculoskeletal pain conditions have often been trained from a biomedical understanding and find it challenging to deliver psychologically informed care including the use of self-management supportive communication (Cowell et al., 2018, 2021; Denneny et al., 2020; Galea Holmes et al., 2022; Pincus et al., 2013; Richmond et al., 2018; Synnott et al., 2015). Despite this, or perhaps because of this, our focus group with clinicians revealed a pull for quality development of treatment delivery and no reluctance towards being observed.

Assessment of clinician's delivery of BCTs has been used widely to investigate fidelity to intervention protocols of self-management and behaviour change interventions, with considerable similarities regarding the choice of BCTs (Beck et al., 2016; French et al., 2015; Harman et al., 2014; Keogh et al., 2015; Lawford et al., 2019; Mars et al., 2013). Similar to our checklist, others combined the assessment of BCTs with items related to communication style (Keogh, Matthews, & Hurley, 2018; Keogh, Matthews, Segurado, & Hurley, 2018; Lawford et al., 2019). It is well documented that clinicians' communication styles hold the potential to not only support and heal, but also to cause harm (Lawford

et al., 2019; Linton, 2015; Stilwell et al., 2021; Synnott et al., 2015), or in other terms, to be need-supportive or need-thwarting (Bartholomew et al., 2011). To capture this, we defined some indicators that would identify if clinician behaviours were in opposition to the intention of the intervention. This resembles the approach used in The Validating and Invalidating Behaviour Coding Scale that codes both *validation* (understanding and accepting the patient's experiences, feelings, actions and worries) and *invalidation* (communicating that what a person feels, thinks, wants or does is strange, questionable or wrong; Holopainen et al., 2023). Although, GLA:D Back was based on social cognitive theory, particularly addressing self-efficacy, the items of the SMAC Checklist resemble the content of the newly developed Classification of Motivation and Behaviour Change Techniques made for self-determination theory interventions (Teixeira et al., 2020).

In addition to capturing unwanted behaviours, we observed that wanted BCTs could be delivered as defined by the BCT taxonomy yet conflicting with the intentions of the GLA:D Back program. Therefore, we found it helpful to code BCTs not only as present or absent but also, if in alignment with the intention when present. For instance, the BCT *instruction on how to perform a behaviour* could be delivered, but without leaving room for the patient to experiment with movement and finding individual solutions.

The development of the checklist followed the most recent recommendations for the development of fidelity measures for complex interventions (Walton, Spector, Williamson, et al., 2020). The SMAC Checklist is, however, intended for use across all patient education and exercise sessions which contradicts the recommendation to develop specific checklists for each session. We decided on a generic design, because the central elements of *adherence* as well as *competence*, potentially could be delivered in all sessions. Also, elements of patient education, for instance, key messages or autonomy-supportive communication style, are expected to be repeated and/or referred to across all sessions in the intervention. The generic design of the SMAC Checklist leaves room for the clinician to adapt the focus and content for each session to the local context and to what matters the most for the participants without risking a poor fidelity evaluation outcome (McHugh et al., 2009; von Thiele Schwarz et al., 2021).

The integration of well-defined BCTs and communication items identified from other studies strengthens its potential for broader use, and the use of 'real world' clinical observations in the development ensured its feasibility. However, some limitations should be acknowledged. First, many BCTs were initially identified as relevant for the fidelity assessment and the number was reduced by prioritizing their importance based on the research group's interpretation of the existing evidence regarding self-management support (Kjaer et al., 2018). However, the impact of specific BCTs on LBP outcomes is largely unknown, and the cut-point for including items was set arbitrarily thus future insights may lead to another selection. In advocacy of the choices made, clinicians delivering GLA:D Back supported all quality indicators included in the checklist.

The SMAC Checklist is intended for expert evaluation of the delivery of care, and it is therefore not a concern that the involved observers had special prerequisites for using the checklist. If the SMAC Checklist at some point is to be used by clinicians' peer evaluation or clinicians' self-assessments, it would have to be amended and evaluated for that purpose. Also, the checklist considers treatment delivery and further developments are to be made if all domains of fidelity described in The National Institutes of Health Behaviour Change Consortium treatment fidelity framework are to be covered, especially with regards to patient receipt and patient enactment (Borrelli, 2011).

Attention towards treatment delivery, not only in research settings but also in clinical practice, is needed to evolve clinicians' competencies in delivering best-practice care.

With the SMAC Checklist, it is our intention to provide a tool for obtaining specific knowledge about clinicians' delivery of care, which we plan to contribute to with a nationwide evaluation of the delivery of GLA:D Back. Such fidelity assessments can potentially identify targets for new clinical skills training programs to be developed and tested.

The next step is to assess the interrater reliability of the checklist, and future studies should investigate the impact of treatment delivery on patient outcomes.

CONCLUSIONS

We developed the SMAC Checklist for the assessment of the delivery of a self-management supportive intervention for people with persistent back pain with the intention that it can be useful also as an adaptable tool for use in other chronic MSK conditions or more broadly. This checklist can be used for determining the level of fidelity in the delivery of the GLA:D Back programme and for identifying aspects of delivery that are challenging within self-management supportive care. This will inform improved training of clinicians in the delivery of self-management supportive patient education and exercise therapy more generally.

AUTHOR CONTRIBUTIONS

Bibi Dige Heiberg: Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; validation; writing – original draft; writing – review and editing. **Inge Ris:** Conceptualization; funding acquisition; methodology; supervision; writing – review and editing. **Henrik Hein Lauridsen:** Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; supervision; validation; writing – review and editing. **Jan Hartvigsen:** Conceptualization; funding acquisition; investigation; methodology; resources; validation; writing – review and editing. **Corrie Myburgh:** Conceptualization; data curation; formal analysis; funding acquisition; methodology; resources; supervision; validation; writing – review and editing. **Alice Kongsted:** Conceptualization; data curation; formal analysis; funding acquisition; methodology; resources; supervision; validation; writing – review and editing.

ACKNOWLEDGMENTS

The authors would like to thank the participating clinicians for their enthusiasm and dedication to this study, and the study participants for their contribution to improving knowledge in this area. The author would also like to thank Orla Lund Nielsen, Rikke Arnborg Lund, Tonny Elmose Andersen, Per Kjaer and Line Thomassen whom all made valuable contributions to the study.

FUNDING INFORMATION

This paper presents independent research funded by the Danish Physiotherapists' Foundation. AK's position at the University of Southern Denmark is partly funded by the Foundation for Chiropractic Research and Post-graduate Education. IRH's position is financially supported by income from clinician training in GLA:D Back.

CONFLICT OF INTEREST STATEMENT

All authors declare no conflict of interest. The researchers were independent of the funder and there were no conflicts of interest, relationships, or activities that influenced the submitted work. The views expressed in this publication are those of the author(s) only.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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How to cite this article: Heiberg, B. D., Ris, I., Lauridsen, H. H., Hartvigsen, J., Myburgh, C., & Kongsted, A. (2023). The GLA:D BACK self-management adherence and competence checklist (SMAC Checklist)—Development, content validity and feasibility. *British Journal of Health Psychology*, *28*, 1052–1075. https://doi.org/10.1111/bjhp.12668

APPENDIX 1

PRELIMINARY FIDELITY FRAMEWORK

Preliminary Fidelity Framework listing a gross list of all potential items including, Item number, Item name, Impact factor, and description of amendments for each item during item selection.

Item name	Impact factor	Amendments during item selection
Behaviour change techniques		
1.1 Goal setting (behaviour)	4,6	Removed by AK & A RESEARCH ASSISTANT, not relevant because it takes place at the individual session
1.2 Problem-solving	4	
1.4 Action planning	2,4	Removed—score < 2,5
1.5 Review goal	**3,8**	
1.6 The discrepancy between current behaviour and goal	1,2	Removed—score < 2,5
2.2 Feedback on behaviour	2,4	Removed—score < 2,5
2.4 Self-monitoring of outcome(s) of behavior	1,4	Removed—score < 2,5
2.7 Feedback on outcomes of behaviour	3,8	Removed—overlap to BCT 10.4/Item 25
3.1 support - unspecified	**4,8**	
4.1 Instruction on how to perform the behaviour	**3,8**	
4.4 Behavioral experiment	**4**	
5.1 Information about the health consequences of the behaviour	**2,8**	
5.6 Information about emotional consequences	3,0	Removed, covered by item 44
6.1 Demonstration of the behaviour	4,2	Removed—not relevant to assess because it is inherent in the GLA:D Back structure
6.2 Social comparison	**2,6**	
10.4 Social reward		Added as a substitute to 2.7 (consensus decision with research team)
8.1 Behavioral practice	2,2	Removed—score < 2,5
8.2 Behaviour substitution	2,0	Removed—score < 2,5
8.6 Generalization of the target behaviour	2,4	Removed—score < 2,5
8.7 Graded tasks	3,8	Removed—implicit in the GLA:D structure
11.2 Reduce negative emotions	2,7	Removed—covered elsewhere (41, 44 + key messages)
13.2 Framing/Reframing	**3,6**	
15.1 Verbal persuasion about capability	**3,8**	
GLAID back key messages		
The back is made for movement	**3,4**	
The back is strong	**3,4**	
The brain can turn pain up and down	**4,6**	
Pain = alarm, not harm	**4,6**	
Bad postures and deformations are common	**4,2**	
Natural movement inhibits pain	**3,6**	

Item name	Impact factor	Amendments during item selection
Exercise strengthens the back	2,6	Removed—contradicts item 34
Actions come before improvement	**4**	
Balancing resources Capacity >< loads	**4,4**	
Communication style		
Familiarizing with the participants	1,2	Removed—score < 2,5
Enact B4. Uses conversational tone	**2,8**	
Enact B2. Provides examples from daily life to explain information/strategies, which are relevant to the topic of discussion	2,2	Removed—score < 2,5
CERT 3. Staying silent	**3,2**	
eNACT A2. Provides reflective summaries of participant contributions which highlight the most relevant point(s)	4,6	Removed—not GLAID specific
eNACT C1. Demonstrates empathy towards group participants	3,6	Removed-not GLAID specific
Patient-centred guidance	**3,8**	Reworded (shared decision-making)
BECCI 5. The practitioner asks questions to elicit how the patient thinks and feels about the topic	**4,2**	
BECCI 10. The practitioner actively conveys respect for the patient's choice about behaviour change	2,2	Removed—covered by item 38
CERT 10. Provide opportunities for patient input or choice	4,6	Covered indirectly by items 38, 39, 42 & 44
CERT11. Use Autonomy Supportive Phrases Instead of Controlling Language	**4,6**	
Enact A1. Displays knowledge and understanding of material/content covered during the session	**4,6**	
CERT 9 Providing a rationale	2,8	Removed–covered by BCT 5.1 & item 40
Paternalistic guidance	**4,2**	
CFT Provides mixed messages - reinforcing fear and biomedical beliefs	**4,8**	
CFT Dismisses or is not attentive to the person's pain and distress	**3,6**	
CFT Reinforces the belief that pain is dangerous and that passive treatments are needed	3,8	Removed—covered by item 45
New items added during content validity		
Adherence		
Time of observation	N/A	
Clinic name	N/A	
Clinic Post No.	N/A	
Number of clinicians	N/A	
Completed form for each clinician?	N/A	
What session was observed?	N/A	
How many people participated in the session?	N/A	

Item name	Impact factor	Amendments during item selection
The number of cancellations?	N/A	
The number of no-shows?	N/A	
How many minutes did the session last?	N/A	
7b. Comment on session duration	N/A	
The clinician is physically present during the séance. The clinician only briefly leaves the room and does not carry out any other tasks related to the séance	N/A	
The clinician is GLA:D Back certified	N/A	
All participants received individual sparring during the session	N/A	
The clinician facilitated group discussions during the session. For example, how did it go lately?	N/A	
Were the sessions started with a group collection? (only relevant for training sessions)	N/A	
Were there indications of deviations from the basic structure of the GLA:D Program? Order, session count, and session types must be correct	N/A	
Describe deviations	N/A	
The clinician refers to posters	N/A	
The clinician uses PP slides	N/A	
The clinician uses laminated sheets	N/A	
The clinician refers to the content in the training folder	N/A	
The clinician uses reflection exercises, e.g., volume button or resource flick (Not relevant for training)	N/A	
Global assessment questions		
The clinician delivers the observed session following GLA:D Back the principles!	N/A	
The clinician delivers the observed session with excellent quality!	N/A	
Additional comments on the observed practice?	N/A	

Note: Items marked in bold are included in the final checklist.

APPENDIX 2

THE DELIVERY OF SELF-MANAGEMENT SUPPORTIVE CARE CHECKLIST

Basic information		
Time of observation:		
Name of the clinic:		
Clinic postal code.		
How many clinicians are leading the session?		
Is there a form filled out for each clinician?	Yes	No

What type and number of sessions are observed?					
How many patients participate in the session?					
The number of cancellations?					
The number of no-shows?					
How many minutes is the recording?					
Comments on recording quality, duration or other technicalities?					
Does the clinician adhere to the GLA:D Back the model?					
The clinician is physically present during the session *The clinician only leaves the room briefly and does not perform other tasks in parallel with the session.*	Yes	No		Not relevant	
The clinician is GLA:D Back certified	Yes	No		Not relevant	
All participants receive individual guidance during the session	Yes	No		Not relevant	
The clinician facilitates group discussions during the session *The clinician asks the group "how have you been since the last session?"*	Yes	No		Not relevant	
The session begins with a group gathering. (only relevant for training sessions)	Yes	No		Not relevant	
Are there any indications of deviations from the basic structure of the GLA:D Program? (Both orders, number of sessions, and session types, session duration must be correct)	Yes	No		Not relevant	
Describe deviations					
Are GLA:D Back materials used?					
The clinician refers to posters	Yes	No		Not relevant	
The clinician uses PP slides	Yes	No		Not relevant	
The clinician uses laminated sheets	Yes	No		Not relevant	
The clinician refers to the content of the exercise program	Yes	No		Not relevant	
The clinician uses reflection exercises, e.g., volume knob or resource tilt (Not applicable to exercise sessions)	Yes	No		Not relevant	
Behaviour change techniques					
Problem-solving—the clinician facilitates that the participant finds solutions to a specific problem *Helps the participant find alternatives to walks such as doing exercises when the weather is bad or acquiring an exercise bike*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
The clinician facilitates the evaluation of the participant's SMART goals *The clinicians ask about the participant's personal goals.*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
The clinician provides personal support, guidance, or counselling, including cognitive behavioural therapy techniques, reflective questioning techniques, and motivational interviewing *The clinician uses the reflective questioning technique e.g., "You told me that you have been in less pain the last few weeks, what do you think about that?".*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++

The clinician instructs the patient on how a particular behaviour is performed *The clinician tells the patient how to do abdominal exercises", or "the clinician instructs the patient on the principles of progression of exercises"*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
The clinician encourages participants to experiment with behaviour, including performing exercises in different ways *"Can you do the abdominal exercises differently, so it doesn't hurt your neck?" "How would it feel if you round or twist more in the back during that exercise?"*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
The clinician facilitates that participants compare their behaviours with the behaviour of others *Draws the participants' attention to how a participant sits and stands or asks a participant to talk about how he gets breaks from his work*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
The clinician praises and acknowledges the behaviour of the participant or participants verbally *The clinician tells the participant that they do well in training. The clinician praises that the participant has cycled to work and taken the stairs*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
The clinician facilitates the reduction of negative feelings, such as stress symptoms, pain and anxiety about movement *The clinician does relaxation exercises focusing on breathing to reduce stress symptoms, or address the participant's concerns directly*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
The clinician facilitates that the participants get new perspectives, and insights concerning a specific situation or problem *The clinician asks how the participant can get a good life with pain and focuses on the participant's values. Or the clinician asks for insights related to the participants thinking about pain?*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
The clinician persuades the participant to believe in their abilities in terms of mastery of back problems *The clinician tells the participant that the back is strong and that he/she can get in good physical shape even if they have back pain*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
The clinician teaches knowledge related to back pain *The clinician talks about the prognosis of back pain and explains the concept of "benign back pain"*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
Key messages (The following (or very similar) formulations are used by the clinician in the conversation with the participants)					
"The brain can turn pain up and down"	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
"Pain = alarm, not harm"	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++

"(Natural) movement inhibits pain"	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
"Balance between resources > < loads"	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
"The back is strong"	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
"Bad posture is common"	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
"Action comes before improvement"	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
"The spine is made for movement"	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/-	+	++
Communication style					
The clinician facilitates that the participants make decisions about their behaviour based on the participant's preferences and values *"What types of activity do you like to do?"; "Now you've mentioned 3 different types, which one do you think we should choose as your activity?"*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
The clinician uses wordings that support the patient in self-determination, rather than dictating language *"You know what's best for you in that particular situation"*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
The clinician appears as a credible source and seems confident in the dissemination of knowledge *"Research shows that…" "it is my experience, that…"*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
The clinician reassures the participants *"You can be completely safe, your back can tolerate that exercise"; "relapse with worsening pain is quite normal", and "exercise soreness is a natural response when starting a new form of training".* *"Keep in mind that pain acts as an alarm that may have become extra sensitive over time"*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
The clinician listens to the participants and leaves room for the participants to talk *"Try to say something more about what happened yesterday when you had pain…"*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/-	+	++
The clinician employs an easily understandable everyday language *"Have you guys had any good days since we were here last?"*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++
The clinician asks about the participants' thoughts and emotions *"What do you think about the fact that you don't have back pain at all anymore/about the pain you're getting now?" "… and how does it make you feel?"*	Yes	No		Not relevant	
Compliance with GLA:D Principles?	−−	−	+/−	+	++

Unwanted behaviour					
The clinician gives contradictory information to the participants *"The back is a strong structure, but you shouldn't turn and bend simultaneously" or the clinician says at one point that back pain is complex and does not have a structural explanation, but subsequently says that "it's your discs that are worn out"*	Yes		No		
The clinician appears authoritarian and paternalistic Controlling/better-/omniscient, *e.g., "You must do these exercises and train at least 4 times a week". "Avoid bending over that way, it might cause harm to your back"*	Yes		No		
The clinician rejects or is inattentive to people with pain/anxiety *A participant says that he gets pain during a specific exercise, but the clinician ignores the information and moves on to talk about something else*	Yes		No		
Overall rating (Quality in general back treatment versus GLAID Back principles)					
The observed session is delivered following GLA:D Back the principles?	Completely disagree	Disagree	Both/Yes	Any	Completely agree
The observed session is delivered with good quality according to current best practices?	Completely disagree	Disagree	Both/Yes	Any	Completely agree
Additional comments on the observed practice?					