



Healthcare Education

Evaluation of a training programme for primary care providers to offer brief behaviour change counselling on risk factors for non-communicable diseases in South Africa

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ABSTRACT

Objective: To evaluate the effect on clinical practice of training primary care providers (PCPs) in an approach to brief behaviour change counselling (BBCC), integrating the 5As (ask, alert, assess, assist, arrange) with a guiding style derived from motivational interviewing in the South African context. BBCC was focused on the four risky behaviours (unhealthy eating, tobacco smoking, physical inactivity, harmful alcohol use) for non-communicable diseases.

Methods: It was a before-and-after design, recording BBCC skills at baseline, directly after training and 6-weeks later. We evaluated each recording for adherence to the guiding style and delivery of the 5As using the Motivational Interviewing Treatment Integrity 3.1.1. tool, and a tool based on the 5As training design.

Results: 123 recordings were collected from 41 PCPs. Results showed a significant improvement in adoption of the guiding style (e.g. global score at baseline 2.0 (2.0–2.6) and in clinical practice 3.0 (2.7–3.3) $p < 0.001$) and completion of the 5A steps (e.g. assist score at baseline 1.26 (1.12–1.4) and in clinical practice 1.75 (1.61–1.89) $p < 0.001$).

Conclusion: Training PCPs in this approach to BBCC is effective at changing their clinical practice in the short term.

Practice implications: The training programme should be integrated into the curricula of PCPs, and used in continuing professional development.

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1. Introduction

Non-communicable diseases (NCDs) are the leading cause of mortality globally, contributing to 60% of all deaths, with nearly 80% occurring in the developing world [1]. Between 1990 and 2013, the numbers of deaths from NCDs and injuries steadily increased, while deaths from communicable, maternal, neonatal, and nutritional causes decreased [1]. Formerly thought of as diseases of affluence, it is expected that the largest increase in NCD deaths will occur in low and middle income African countries, where they will contribute to 70% of deaths by 2020, and be the most common cause of death by 2030 [2]. South Africa is faced with a transition in the burden of disease as the dominance of chronic infectious diseases, such as HIV/AIDS and tuberculosis, is

rivalled by the growing prevalence of NCDs, such as hypertension and type 2 diabetes [3,4]. The scaling up of the HIV treatment programme has also resulted in longer life expectancy, which increases the number of people at risk of developing NCDs. This has led to an increased prevalence of NCDs in all communities, disproportionately affecting poor people living in urban settings, and placing an increasing demand on chronic care delivery [5]. The risk factors associated with NCDs have been clearly identified and confirmed locally [6,7]. Tobacco smoking, excessive alcohol consumption, lack of physical activity and unhealthy diet are the key modifiable factors contributing to morbidity and mortality from NCDs [8,9].

Health services in low and middle income countries, such as South Africa, are based on a model of treating acute illness, and are not organised for the prevention and on-going management of NCDs. The need for integrating the care of chronic diseases into primary care, has recently been recognised by the National Department of Health in their strategic plan for NCDs [10]. Ambulatory primary care is dominated by patients presenting with NCDs,

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and multi morbidity is common [11]. Although behavioural interventions that target multiple risk factors have been demonstrated to improve risk factors for diabetes and hypertension they are not given priority in the existing health system [12]. Shifting the focus of primary care systems from an acute to chronic care model is a complex task, and all levels of the system need to work together to successfully implement, support and coordinate chronic care [3,13].

The internationally recognised chronic care model acknowledges the need for change, not only at the system level, but also at the level of the consultation [14]. It is recommended that primary care providers shift away from the traditional, directive approach to counselling patients with risky lifestyle behaviours and adopt a more patient-centred style. A directive style assumes that it is the provider's responsibility to convince the patient on what, and how to change [12]. This approach often results in resistance from the patient and frustration from the provider as patients do not change when they expect them to [15]. In current best practice recommendations, however, the patient is regarded as the expert in deciding if and why they should change their lifestyle, and the PCP acts as an expert guide, working collaboratively with the patient to support self-management [13].

Self-management support involves assisting the patient by guiding them in problem solving, decision-making, resource utilisation, forming a patient-health care provider partnership and taking action [13]. Several approaches can be used to support the patients' self-management [13]. For example, in our local context, a group self-management programme for people with diabetes delivered by health promoters, reported behaviour change and was shown to be cost-effective [15–17]. However, brief behaviour change counselling (BBCC), delivered by PCP's to individual patients, as part of the normal consultation is also an effective way of assisting patients [15,18]. Individual BBCC should be actively integrated into everyday primary care and, therefore, training is required to enhance practitioners' perceptions of the value of changing their consultation style, their ability to succeed, and to provide them with the necessary skills [6,8,19].

South Africa's primary care services are primarily nurse led, and appropriately trained nurses with doctors playing a supportive and reinforcing role, can deliver high quality preventative care [20]. Currently the local training of PCPs on BBCC is not designed to achieve competency, and PCPs lack confidence in their ability to perform BBCC [15]. Apart from insufficient training, PCPs are also faced with numerous other barriers, including language barriers, lack of time, poor content knowledge of lifestyle modification, poor continuity of care, and their expectations of patient non-adherence [12,15]. Redesigning the current training programme was therefore deemed necessary in order to improve BBCC as a component of chronic care [15].

The ADDIE process provided a systematic approach for the Analysis of learning needs, the Design and Development of the training programme, its Implementation and initial Evaluation [21]. The overall aim was to ensure that PCPs were trained to use a best practice BBCC method for patients with risky lifestyle behaviours that included screening for risky behaviour, providing evidence-based accurate information, assessing readiness to change, and offering effective guidance or referral. A detailed description of the situational analysis, and the development and implementation of the training programme is given elsewhere [15,21]. This study reports on the initial evaluation of the effectiveness of the training intervention.

There are a number of approaches that can be used to assist patients in changing risky behaviours, such as motivational interviewing, health coaching and the 5As (Ask, Alert, Assess, Assist and Arrange). No single approach is superior to the other, in fact they often complement each other and most BBCC training

programmes are designed by using a combination of approaches [13]. Very few of these training programmes assess the effectiveness of the training, by measuring primary care providers performance before and after the training programme [22–24]. A possible reason for this could be that each programme is unique in terms of content, duration, target audience and setting, and therefore no standardised tool to assess the effectiveness of all BBCC programmes currently exists. To our knowledge, this was the first time that a training intervention for BBCC, based on models found to be successful in high-income countries, was developed for our setting, and tested in an African context. The specific objectives of this study were to:

- Evaluate the ability of PCPs to demonstrate BBCC at the end of the training course.
- Evaluate the ability of PCPs to incorporate BBCC into actual clinical practice.

2. Methods

2.1. Study design

The study was a before-and-after study design with evaluation of BBCC skills at baseline, directly after training and six weeks later when participants had returned to their clinical practice.

Participants consulted a standardised patient who presented with one of the four risky lifestyle behaviours, immediately before, and immediately after the training intervention. Six weeks later, participants were again consulted and recorded by a standardised patient at the clinic where they worked, however the trained participants were blinded as to the identity of the patient within their normal clinical workload.

2.2. Study participants and setting

The study was conducted within the context of the primary care system in the Western Cape, where the majority of patients are seen in the public sector by clinical nurse practitioners in either small clinics or larger health centres. The public sector primary care system is struggling to develop a culture of patient-centeredness and to provide some form of continuity of care. Patients in the public sector are uninsured and come from low educational and socio-economic backgrounds, while patients in the private sector are usually employed and insured, or can afford out-of-pocket payments. In the private sector care is usually provided by a general practitioner [25].

Our study participants included primary care doctors and clinical nurse practitioners. The primary care doctors included medical officers working in the public sector, general practitioners working in the private sector, or family physicians. Family physicians have 4-years of postgraduate training, while working as a registrar in the public sector and registered with either Stellenbosch University or the University of Cape Town. The clinical nurse practitioners were receiving training through the 1-year Diploma course (Diploma in Clinical Nursing Science, Health Assessment, Treatment and Care) at Stellenbosch University.

2.3. Sample size calculation and sampling strategy

A sample size of 40 individuals was calculated to have 86% power to detect a change of 0.1 on the global rating, assuming a standard deviation of 0.2. A sample size of 20 nurses and 20 doctors was therefore recommended, but to compensate for attrition we aimed to include 25 from each group.

Participants were recruited by advertising it as a short course to family medicine and nurse training programme managers, family

physicians, medical officers, family medicine registrars, general practitioners, and nurses on the Diploma course. Participants were excluded from the study if they could not be followed up for the third recording at PHC clinics in the Cape Metropolitan or rural area, after the training, or if they did not consent to participate in the study.

2.4. Training intervention

The training course integrated two behaviour change approaches, the 5 As and a guiding style derived from motivational interviewing (see Table 1), which are both well supported in the scientific literature on behaviour change counselling [13,19,26,27]. The 5 As provided a simple structured approach, incorporating elements of the guiding style into each of the five steps, in order to enhance patient centeredness. In other words a guiding spirit of “allow me to help you sort this out for yourself”. The training was designed as an eight hour workshop, with four two-hour sessions, in order to fit into the time available in the participant’s curricula or clinical practice. Each session was developed using three key principles: to provide evidence of the current deficiencies and the need for a new approach, to model the approach and allow participants to practice new skills.

2.5. Data collection process

A group of six standardised patients were purposefully selected and recruited from the available pool of actors at the Division of Family Medicine and Primary Care, Stellenbosch University. They were trained to present one of the four behavioural risk factors in a specific role play. Inclusion criteria stipulated that they had to simulate the usual patient population seen by PCPs and that they had the ability to reliably role play. Each PCP was recorded whilst counselling a different standardised patient, directly before training, directly after the training, and six weeks later in their clinical practice. In their clinical practice the standardised patients inserted themselves into the queue of normal patients waiting to see the practitioner, and were seen as part of the usual clinical workload. The PCPs were therefore blinded as to the identity of the standardised patient in their clinical practice and unaware of the day on which they would attend.

Each recording was evaluated for both guiding style as well as the delivery of the 5 As. For the guiding style we used the Motivational Interviewing Treatment Integrity (MITI 3.1) tool, which is a validated instrument that can be used for evaluating competence in MI [28]. It can be used as an assessment of whether a candidate has reached beginning competency or proficiency, but

also to evaluate the effects of training and skills development of a practitioner over time. The MITI 3.1 can be effectively used to assess shorter interventions, such as those typically used in BBCC [28,29].

To use the MITI 3.1 tool, a coder listens to a recording, and scores the tape in two sections; global scores and behaviour counts. The first section focusses on three global scores for autonomy, evocation and collaboration, which characterises the guiding style. Autonomy measures the extent to which the counsellor supports the patient’s choice and sense of control, whilst evocation measures the ability of the counsellor to elicit the patient’s own motivation to change. Collaboration measures the extent to which an equal partnership is formed. The final global score is a mean of these three values on a Likert scale from 1 to 5 that aims to capture the coders overall impression of the session. Global scores less than 3 indicated a more directive style, whilst higher scores demonstrated a guiding style. The second section counts the frequency of specific counsellor behaviour in five categories (MI adherent utterances, MI non-adherent utterances, information-giving, questions and reflections). MI adherent statements are consistent with the MI approach, for instance asking permission before giving advice, whilst non MI adherent statements are not, for instance, blaming the patient. Two of these categories include subcategories (closed and open questions, and simple and complex reflections). Open ended questions allow for a range of possible answers, whilst closed questions; require a simple yes or no answer. Reflections involve rephrasing a statement to capture the implicit meaning. A simple reflection adds little meaning to the patient’s talk, whilst a complex reflection adds substantial meaning. The behaviour counts are then summarised in four calculated scores (% MI adherent statements, % complex reflections, % open questions and the ratio of reflections to questions). For all scores the MITI includes thresholds that indicate basic competency or full proficiency [30].

A few studies have used audio recorded data to evaluate the 5 A’s for physical activity and smoking cessation, but to our knowledge no study has evaluated the delivery of the 5 A’s adapted to incorporate elements of the guiding style into each of the steps from audio recordings of counselling for any of the four main NCD risk behaviours [31].

We developed and used a simple observational tool to assess the delivery of the 5 As for all four risk behaviours. A draft tool was developed by the principal researcher based on the learning outcomes for each step of the 5 As in the training manual. Feedback was then obtained on the content and construct of the tool by the other authors who are experts in behaviour change counselling. The revised tool was then piloted by the researcher and the final

Table 1
Integrated 5 A steps with a guiding style approach.

Step	Criteria
Step 1: Did the PCP ask about the risky behaviour?	<ul style="list-style-type: none"> • Asks about risky behaviour • Asks permission to discuss the issue • Asks what the patient already knows, or wants to know
Step 2: Did the PCP alert the patient to the risk?	<ul style="list-style-type: none"> • Provides information in a neutral way • Provides information tailor made to the patients’ needs • Elicits the patients understanding of the information provided
Step 3: Did the PCP assess readiness to change?	<ul style="list-style-type: none"> • Assesses importance of change • Assesses the patients confidence to change • Uses scaling questions correctly/appropriately
Step 4: Did the PCP a. Provide any practical assistance to help the patient change? b. Ask the patient to think about changing in the future?	<ul style="list-style-type: none"> • Discusses different options available with the patient appropriate to their readiness to change • Respects the patients autonomy in their decision/choice • Provides relevant practical assistance such as educational leaflets/telephone numbers/prescription
Step 5: Did the PCP a. Arrange for follow up? b. Open the door for the patient to come back in the future?	<ul style="list-style-type: none"> • Arranges for follow up appointment • Demonstrates a willingness to offer ongoing support • Explores how to involve the patient’s social support system such as friends or family

Table 2
Evaluation of the guiding style at baseline, post-training and in clinical practice.

MITI criteria	Baseline (1) Mean (95%CI)	Post-training (2) Mean (95%CI)	Clinical practice (3) Mean (95%CI)	p-value (1–3)	p-value (1–2)	p-value (2–3)
Global score (1–5)	2.3 (2.0–2.6)	3.4 (3.1–3.7)	3.0 (2.7–3.3)	<0.001	<0.001	0.01
Motivational interviewing adherence (%)	41.3 (32–50)	88.7 (79.3–98.0)	66.7 (57.3–76.0)	<0.001	<0.001	<0.001

anchors were defined for each score (0, 1 or 2) for each of the 5 steps. For each step in the 5 As three integral tasks were identified as per the training manual and participants were scored according to the extent to which they completed all three tasks (Table 1) [21]. If they performed none of the integral tasks at the specific step, they scored 0, if they performed one or two tasks they scored 1 and if they managed to perform all three tasks, they scored 2. Tasks could be completed by the practitioner explicitly or by the patient implicitly completing the task. For example the patient might reveal their risky behaviour to the practitioner without being explicitly asked. We also realised that the sequence of the delivery of each of the steps of the 5 As was important, for instance, assisting a patient before assessing readiness to change was scored as inappropriate, by deleting all the awarded points for the inappropriate step [32].

2.6. Data analysis

The analysis was performed in Statistica version 12 (Statsoft 2014) with the help of the Centre for Statistical Consultation, Stellenbosch University. Repeated measures analysis of variance (ANOVA) was used to compare data from all three time points (baseline, post training and in clinical practice). For the MITI tool we compared data using the mean total global score and the mean score for each of the five behaviour counts. For the 5 As tool, we compared the mean score for each of the five steps for each recording. The 95% confidence interval was also calculated for each mean. Where statistically significant differences over time occurred a post hoc Bonferroni test was performed to evaluate which comparison was significantly different. The risk of error was set at 5% ($p = 0.05$).

Inter-rater reliability was tested for the MITI 3.1 tool by randomly selecting a sample of 20 recordings across all time points and comparing the scores obtained by the researcher with an international independent rater who was an expert in using MITI 3.1. Analysis calculated the Spearman correlation for the scoring between the two raters.

2.7. Ethical considerations

Ethical approval was obtained from Stellenbosch University, Health Research Ethics Committee (N11/11/321) on 27 February 2012, as well as permission from the Department of Health, in the Western Cape (RP 029/2013) Participants were informed and consented before the first recording that took place on the morning of the 8 hour training.

3. Results

A total sample of 123 recordings was collected from 41 participants. During 2012–2013 three groups of nurses and three groups of primary care doctors completed the training programme which was run at Stellenbosch University. Twenty-three nurses on the 1 year Diploma course at Stellenbosch University, 12 family medicine registrars during their second year of training at the Universities of Stellenbosch or Cape Town, two general practitioners in private practice in Cape Town, and four family physicians working in the rural areas of the Western Cape were trained.

Overall 82% were females and 55% of the participant's spoke Afrikaans¹ as their first language, 37% English and 8% Xhosa.²

Table 2 presents the results on the extent to which participants adopted the guiding style. The most important comparison is from baseline to clinical practice (recording 1 vs. 3), because this shows what participants retained over time in every day clinical practice. The global score and behaviour counts all showed a statistical significant improvement from baseline to both post training and clinical practice. Although none of the participants met the thresholds for beginning competency in the use of motivational interviewing, the mean score after training almost reached this threshold and subsequently decreased over time. The decrease in proficiency from the end of training to clinical practice was statistically significant for the global score and adherence to MI. It should be remembered however that the training programme was not intended to teach competency in MI but to develop the guiding style and the improvement in global score and adherence to MI principles would suggest that this was achieved. We showed good inter-rater reliability for the global score (spearman = 0.61), MI adherence (spearman = 0.74) and reflections to questions ratio (spearman = 0.64), but poor reliability for %complex reflections (spearman = 0.29), and %open questions (spearman = 0.2). The results for %complex reflections and %open questions are therefore not presented. The areas which were of more importance to measure in terms of demonstrating a guiding style, however, showed good inter-rater reliability [28].

Table 3 demonstrates that for the group as a whole, each of the steps in the 5 As protocol improved significantly from baseline to both post-training and clinical practice. All of the steps were recognisable, even at baseline, but there was a statistically significant improvement of performance for each step over time. Since the training and observation tool were designed to incorporate the guiding style into each of the steps, this also suggests that they moved towards a guiding style as a result of the training in addition to completing each step. Arranging for follow up (step 5) was the step performed the most frequently throughout, while assessing a patient's readiness to change (step 3) was lowest at baseline (mean = 0.97) and was the only step to also decrease significantly from post-training to clinical practice ($p = 0.04$).

For each of the steps there was no statistical difference between the performance of the doctors vs. the nurses, except for the assessment of readiness to change in which the overall mean value for nurses was significantly lower than the doctors (nurses 1.26 (95%CI: 1.12–1.39), doctors 1.68 (95%CI: 1.53–1.83), $p < 0.001$).

4. Discussion and conclusion

4.1. Discussion

This was the first study to our knowledge that has evaluated the delivery of a BBCC training programme using the 5 As model adapted to encourage PCPs to use a guiding style in each step when

¹ Afrikaans is prevalent throughout much of the Republic of South Africa but primarily in Transvaal and the Orange Free State. The language arose in the 17th century through a process of integration and intermixing of various dialects.

² Xhosa is the southernmost branch of the Nguni group of African language, mainly spoken in the Eastern and Western Cape provinces of South Africa.

Table 3
Performance of the 5A steps.

5 A Steps	Baseline (1) Mean (95%CI)	Post-training (2) Mean (95%CI)	Clinical practice (3) Mean (95%CI)	p value (1–2)	p value (1–3)	p value (2–3)
Step 1 (0–2)	1.39 (1.24–1.53)	1.9 (1.75–2.04)	1.73 (1.58–1.87)	<0.001	<0.001	0.09
Step 2 (0–2)	1.02 (0.74–1.3)	1.78 (1.49–2.06)	1.63 (1.35–1.91)	<0.001	<0.001	0.23
Step 3 (0–2)	0.97 (0.79–1.15)	1.8 (1.62–1.98)	1.56 (1.38–1.73)	<0.001	<0.001	0.04
Step 4 (0–2)	1.26 (1.12–1.4)	1.92 (1.78–2.06)	1.75 (1.61–1.89)	<0.001	<0.001	0.08
Step 5 (0–2)	1.41 (1.23–1.59)	1.95 (1.76–2.13)	1.87 (1.69–2.06)	<0.001	<0.001	0.49

counselling patients on any of the four main NCD risk behaviours. Importantly this was also the first evaluation of such a training intervention using the 5 As in an African context. The study results suggest that training clinical nurse practitioners and primary care doctors in BBCC is effective in the short term and can result in significant adoption of the 5 As used with a guiding style. This study echoes international findings that have demonstrated that PCPs can be effective in providing BBCC [20].

BBCC has been demonstrated to improve the frequency of preventive care and support for behaviour change, however its impact on health outcomes remains uncertain. This study did not measure the clinical outcomes for patients, and there are not many published studies that have measured patient level outcomes [20,33]. However the little evidence that does exist suggests that behaviour change counselling in a guiding style has a 10–15% increased chance of success in changing a wide range of behaviours [34]. On this basis we can speculate that the statistically significant improvement of PCPs, from a directing to a guiding style, could be clinically meaningful, despite the fact that our participants did not reach MI proficiency.

Our findings were similar to a local study of health promoters, who provided group BBCC to diabetic patients, in that counsellor's ability to guide improved significantly, without achieving MI proficiency. Yet in this study, the health promoters were still shown to have a clinically significant effect on reducing blood pressure [35]. This intervention was also found to be cost-effective [17]. Another local study that evaluated the combination of the 5As and a guiding style delivered by midwives and lay counsellors also demonstrated a clinically significant effect on smoking cessation, although the training was not evaluated and the fidelity of the counsellors to the method in clinical practice was not as rigorously assessed [36].

Evaluation of the 5 As has shown that full implementation of the 5 A steps in the correct sequence shows better outcomes than partial or inconsistent use [37]. For example it is important to assess the patient's readiness to change, because it is a key step in deciding on appropriate assistance and follow up. Our finding that Step 3 "Assessing readiness to change" was the least well implemented task in clinical practice has also been reported in other studies. These studies also reported on PCP's difficulty with assessing readiness to change in the clinical setting [31,32,38]. This suggests that clinician training should particularly focus on PCPs ability to assess readiness to change [31].

Training PCP's to deliver BBCC and evaluating the effectiveness of training interventions are recommended as important components of best practice BBCC training programmes [18,24,38]. However a recent systematic review of 10 MI training studies for general practitioners to deliver lifestyle advice in primary care, showed that there is limited assessment of skills competence, and just two studies considered patient level outcomes [33]. A strength of this study, therefore, is that it measured the skilfulness of PCPs

over time, in terms of competence for both their MI skills, as well as their performance of the 5 A steps, although their performance in clinical practice was not measured beyond six weeks.

Although the MITI can be used for evaluating MI adherence in shorter recordings, it is primarily intended for use in a randomly selected 20 min segment of a longer recording of a MI therapy session [28]. The reliability of the coding may decrease when short segments of less than 20 min are used, as in this study. A third of the recordings were in Afrikaans, which could also be a possible explanation for the lack of correlation in some behaviour counts. The researcher was a first language Afrikaans speaker, whilst the international coder was a first language English speaker, who spoke Afrikaans as a second language. It should also be noted that the researcher, who was trained as a coder by RM and is a member of MINT, coded all the recordings and therefore changes in score over time would reflect a consistent approach to coding. The coder was also blinded as to which time period the recording came from.

The tool to measure the quality of the delivery of the 5 As was an innovation that all the researchers contributed to designing. The design and development of the tool focused on content and construct validity and resulted in an easy to use tool that was congruent with the model of BBCC and the training programme. However, there was no formal testing of its reliability, which may be a useful focus of a future study.

Future research needs to explore whether the shift in counselling style is sufficient to improve clinical outcomes for all four risk factors. Research should also evaluate ways of reinforcing the training during clinical practice and evaluating to what extent the new skills are maintained over time. Although this study found little difference between doctors and nurses, future research may want to explore differences in baseline skills, responses to training and retention of skills between nurses and doctors.

4.2. Conclusion

This study demonstrated that an evidence based 8-h training programme in BBCC can lead to significant change in the approach to counselling in both clinical nurse practitioners and primary care doctors in the South African context. Significant uptake of the counselling skills was seen immediately after training and 6-weeks later in clinical practice. Practitioners significantly improved in their ability to utilise the 5 A steps and to adopt a guiding style.

4.3. Practice implications

The training programme should be integrated into the training of primary care doctors and clinical nurse practitioners [15,27,39,40]. The *ichange4health* programme has helped to further develop the materials and train trainers from Departments of Family Medicine and Primary Care throughout South Africa

[27]. These trainers are now training medical students, general practitioners and other family physicians in their respective areas. Training should also be incorporated into the curricula of clinical nurse practitioners, as they form the cornerstone of primary care. Training programmes should particularly focus on assessing readiness to change as this is the step most likely to be forgotten or avoided during clinical practice.

Author's contributions

All three authors were involved in the conception, design, development and implementation stages. Data collection was mostly done by ZM, whilst all three authors contributed in the analysis and interpretation of data, as well as drafting and revising of the article, and approved the final manuscript.

Conflict of interest

No conflict of interest

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