

PROPELS: Fidelity Standard Operating Procedure (SOPs)

propels



**Walking Away
from Diabetes**

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All tools developed by University of Cambridge to support 'follow on support' fidelity are owned by the University of Cambridge.



Who is this SOP for?

- Trial Co-ordinators at each site will be responsible for ensuring that this SOP is followed and implemented.
- WA Educator **trainers** and **mentors** at each site will be responsible for ensuring that relevant sections of this SOP are implemented correctly.

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1. Overview of fidelity promotion and assessment

Fidelity refers to the extent to which interventions are delivered as planned.

For example, group 2 receives the Walking Away from Diabetes group education sessions, and group 3 will additionally receive **follow on support** in the form of text messages and phone calls. We need to know two things if we want to draw valid conclusions about the effectiveness of Walking Away and the follow-on support intervention, respectively.

1. Were the Walking Away educational sessions and the follow-on support delivered as planned and consistently over time and across all educators?
2. Did groups 2 and 3 differ in the way that they were meant to differ, e.g., group 2 did not receive any text messages?

Unless we know that interventions have been delivered as planned, we don't know whether any lack of effectiveness is due to inadequate delivery (e.g., educators missing out key steps in the phone calls) or inadequacies inherent in the intervention itself (e.g., ineffective behaviour change techniques). It would also be unclear whether any positive outcomes produced by the intervention (e.g., participants increasing physical activity) were due to the planned intervention, or an effective component (e.g., different behaviour change techniques) that educators added to the planned intervention.

Fidelity **promotion** is about the processes put in place in order to ensure that the intervention (the WA education sessions and the follow-on support) is delivered consistently across sites and educators, throughout the course of the PROPELS study.

In practice, it is difficult to deliver interventions **exactly** as planned. The information gathered from fidelity assessments can help the PROPELS research team to better understand the challenges that educators may come across such as:

(a) when and why the intervention may have to be adapted, (b) how participants respond to contacts with educators, which aspects of the intervention work well and which ones not, and how the intervention may need to be adapted in different contexts and settings. Fidelity assessments are not only about finding out whether the intervention was delivered as planned, but learning from how the intervention plays out in practice and how it may need to be adapted in the future.

2. Fidelity of the Walking Away (WA) Group Education Session

A recommended pathway has been developed to support educators to become competent at delivering the Walking Away (WA) Group Education programme. These steps are in place to ensure that educators are at a good standard in delivering WA, as near to the start of the randomised controlled trial (RCT) as possible.

The pathway includes the following steps:

- Educators attend an open evening to find out about the study and intervention.
- Educators observe of a WA course prior to attendance on training course.
- Educators complete a WA work book prior to attendance on training course, including wearing of a pedometer and self-monitoring steps.
- Educators attend a two day programme: CORE day (detailing the philosophies and theories underpinning the programme); and WA day (training specific to the programme) run by two experienced National trainers.
- Provision of a core manual detailing the philosophy of the WA programme, the underpinning theories and educator behaviours.
- Provision of a WA curriculum detailing expected learning outcomes, educator activities, and participant activities, resources to be used and sample script.
- Opportunities prior to the RCT for educators to 'have a go' at delivery so that at the start of the RCT they are at a good standard delivering WA.
- Post WA training there is a pathway of self-reflection, peer reflection and mentorship visits (based on the existing national DESMOND Quality Development pathway).

2i. Mentorship Visits

Once educators are trained to deliver the WA programme, educators at both sites will have an official mentoring visit (after they have run 3-5 WA courses). The mentor will be a member of the National DESMOND training and assessors team. The mentor (Jacqui Troughton or Janette Barnett) will observe the WA from Diabetes course (3.5 hours) and will use National DESMOND Quality Development tools to be able to give structured feedback to the educator. Preferably prior to the mentorship visit, the educator will send completed self and peer reflection forms to the mentor. If not submitted beforehand, the educator needs to bring documentation to the mentorship visit.

When the WA from Diabetes session has been observed, the mentor and educator will meet for a further one hour to discuss what went well, what went less well and make a written action plan.

2ii. Formal Assessment Visit and Accreditation

Once educators at both sites have run 9-10 WA courses, they will have a formal assessment carried out by a member of the National DESMOND training and assessors team. The assessor will use the same documents as used for the mentorship visit i.e. self-reflection forms, peer reflection forms, National DESMOND Quality Development tools.

The assessor (Jacqui or Janette) will observe the WA from Diabetes course (3.5 hours) and will use National DESMOND Quality Development tools. documents to be able to give structured feedback to the educator. If the educator meets the expected criteria (set by the National DESMOND office), they can become accredited DESMOND educators if they so wish.

It is the responsibility of the trial co-ordinators at each site to schedule the mentorship and assessment visits for educators.

2iii. Follow on WA Education Sessions

The pathway for becoming competent to deliver the follow-on group education sessions includes:

- 1 day training.
- Provision of a Follow-on WA curriculum detailing expected learning outcomes, educator activities, and participant activities, resources to be used and sample script.
- Post training there is a pathway of self-reflection, peer reflection and mentorship visits (based on the existing national DESMOND Quality Development pathway).

Mentorship visit

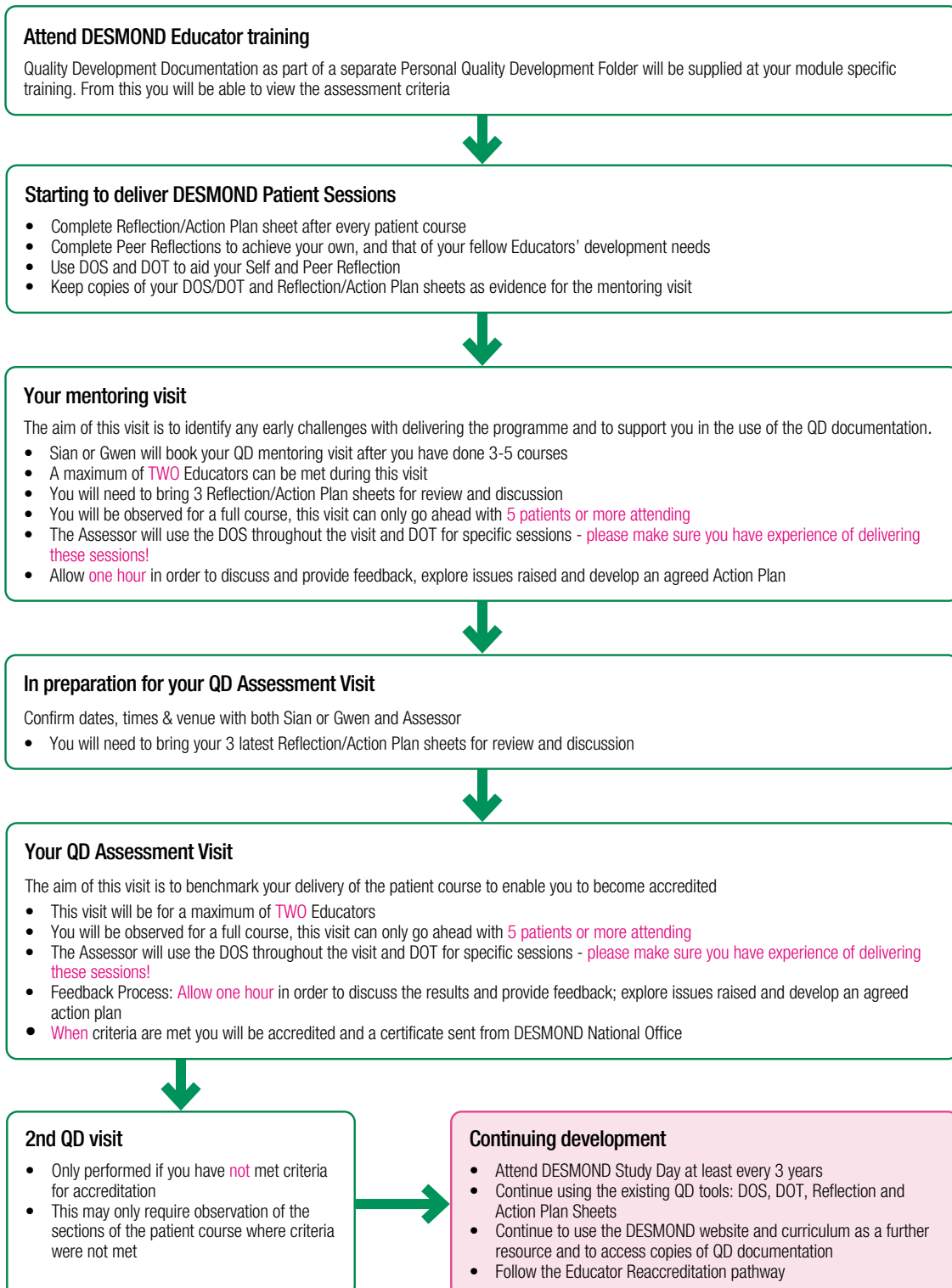
Educators at both sites will have an official mentoring visit after they have run 3-5 follow-on WA sessions each year. This process will be exactly the same as for the initial WA session.



It is the responsibility of the trial co-ordinators at each site to schedule the mentorship visits for educators during year 2 (i.e., after the follow-on education sessions are underway)

2iv. WA fidelity documents and tools:

a. Pathway for educators to ensure competency in WA education session delivery



3. Fidelity of the PROPELS Follow-on Support

In order to ensure that all educators are competent to deliver the PROPELS follow-on support (i.e. the phone calls with participants in between the WA sessions), all educators must receive:

1. 2 X ½ day training for the follow on support intervention (roughly 6 months apart).
2. A core manual (“PROPELS Educator Follow-on Support Curriculum”) detailing the follow on support intervention.
3. Self-reflection forms for educators to complete.
4. On-going mentorship for follow-on support delivery (2 * 45 minute face to face meetings per year with their mentor).

3i. Follow-on support training

All educators will attend the initial follow on support training session (3 hours) that covers the key aspects of the follow-on support intervention. The training aims to enhance competence and confidence to (a) explain the follow-on support programme to participants in group 3 at the end of the WA session, and (b) deliver the initial one week phone call. The second training session (roughly 6 months later) aims to ensure that educators are competent and confident to deliver the 6 months phone call.

The training will be delivered by Jacqui Troughton and Katie Morton. Correspondence with educators to organise these events is facilitated by the trial coordinators at each site.

3ii. Educator follow-on support manual

This manual will be provided to all educators during the initial follow-on support training. It includes a detailed overview of the PROPELS follow-on support intervention, key behaviour change techniques, example text-messages, key steps for the phone calls and information on fidelity promotion and assessment, including copies of the assessment sheets and self-reflection forms.

3iii. Self-Reflection forms

In order to develop and retain the skills required for follow on support delivery, the trial co-ordinator at each site will ask the educators to audio-record ALL the phone calls made and complete the “calls reflection sheet” (see page 14).

The trial co-ordinators will ask the educators to complete the calls reflection sheet for the first ten ‘one-week’ phone calls, and the first ten ‘6-month’ phone calls that they make. They will also encourage the educators to complete the form if they felt a phone call went particularly well or badly, so that this can be utilised in the mentoring session for discussion and training purposes.



It is the responsibility of the trial coordinator at each site to ensure that the educators audio-record ALL phone calls (see “One-week telephone support SOP” and “6-month telephone support SOP”). The trial co-ordinator at each site should also encourage the educator to complete the self-reflection forms for the first 10 ‘one-week calls’ and the first 10 ‘6 month calls’ (provide copies of these sheets if required to prompt the educator to complete these)

3iv. Ongoing mentorship and training

Beyond the initial training session, a local mentor will be the point of contact for the educators who are delivering the WA follow-on support component (i.e., those educators identified to make the follow-on support phone calls). These mentors will be experienced educators: Jacqui Troughton in Leicester and Monica Harris in Cambridge.

Face to face meetings with mentor for ongoing training and support

1. After 3-6 weeks of initial follow-on support phone calls (or after 10 calls have been made; whichever comes first), a 45 minute meeting will be scheduled between the mentor and the educator. This meeting should happen again 3-6 weeks after the 6 month phone calls have started to be delivered. It is the responsibility of the trial coordinator at each site to schedule this meeting.
2. Prior to each meeting, both the mentor and the educator will be provided with 3 randomly selected recordings (the trial coordinator at each site will be responsible for randomly selecting audio-files to review and sending the audio-files and copies of the relevant checklists to educators and mentors).
3. Both the mentor and educator will be asked to listen to the recordings and complete the “core behaviours checklist” (either the ‘one-week’ or ‘6-month’ version) and the key communication skills checklist (see pages 11, 12 & 13) for each recording prior to the meeting. It is anticipated that the mentor will require 1 hour of preparation time for EACH mentor meeting.
4. During the face to face meeting, the mentor will provide the educator with constructive and supportive feedback on how they are doing (by using the completed ‘checklists’ and any completed self-reflection forms completed to date), and help problem-solve any difficulties experienced. Both the educator and mentor will identify ways in which the educator can meet the required criteria for delivery of the phone calls.
5. More frequent support can be provided if the educator is struggling (as assessed from the audio-recordings). Educators can contact mentors via email if they have a question relating to the follow-on support delivery. Where possible, educator will be encouraged to contact other educators (who are also delivering the phone calls) to problem solve together, before contacting the mentor.



In sum, it is the responsibility of the trial coordinator at each site to schedule at least 2 x 45 meetings per year between the mentor and the educators involved in delivery of the phone calls, select audio-files for review, send audio-files and checklists to educators and mentors prior to face-to-face meetings, and log that the meetings have taken place in the trial master file.

3v a. PROPELS Core Behaviours Checklist - WEEK 1



Week 1 Phone Call	Yes/No
Greet participant	
Elicit (from participant) his/her experiences of wearing the pedometer and logging steps during week 1	
Elicit (from participant) information about his/her previous physical activity over the last 12 months	
Ask about importance of increasing physical activity (on a scale of 1-10) <ul style="list-style-type: none"> • Ask how come participant selected this number and not a lower number? • Ask what would need to happen in order in score higher? 	
Ask about confidence to increase physical activity (on a scale of 1-10) <ul style="list-style-type: none"> • Ask how come participant selected this number and not a lower number? • Ask what would need to happen in order in score higher? 	
Ask participant to recall (from education session) how many steps they should be aiming for in order to achieve health benefits.	
Re-iterate PROPELS long-term and short term goals in terms of weekly and daily steps (e.g., long-term = 3000 per day/21,000 per week above baseline; short-term = 500 per day/3500 per week above baseline)	
Explain importance of making small changes to work up to short-term goal initially, and long-term goal over the next 12 months	
Clarify what the participant's long-term and short terms goals are (e.g., specify exact step count that participant is aiming for in terms of daily amount and weekly amount)	
Ensure participant is happy with these step goals	
Confirm participant's action plan (what activity, where and when?)	
Remind participant to record daily steps using the activity diary for next 8 weeks and to text in once per week (once they receive the text from PROPELS)	
Remind participant to use the step converter in the back of the activity diary to record any activities that the pedometer cannot pick up	
Ask if participant has any questions.	

3v b. PROPELS Core Behaviours Checklist - 6 MONTH



6 Month Phone Call	Yes/No
Greet participant and ask how they are (in general)	
Elicit (from participant) their experiences of increasing activity levels over the past 6 months.	
Elicit (from participant) any benefits they have experienced in relation to physical activity over the past 6 months.	
Reinforce the benefits that the participant highlights	
Summarise goal progress over the last 6 months (e.g., using values that the participant has texted in)	
Facilitators: Ask the participant to identify anything that helped them to be active over the past 6 months.	
Problem solving: Ask participants to identify anything that got in their way/barriers to activity.	
Problem solving: Ask participant to think about potential solutions to the barriers they highlight and reinforce these solutions.	
Goal review: Review the original goals set with participant and amend these if required (e.g., set new short term goal for next 6 months)	
Ensure participant is happy with these step goals	
Review action plan (does this need to change since initial phone call; what activity, where and when?)	
Ask about confidence to achieve long term goal over the 6 months (on a scale of 1-10) <ul style="list-style-type: none"> • Ask how come this number and not a lower number? • Ask what it would take for this to increase? 	
Remind participant that they will still receive 2 texts per months (e.g., tips and new ideas for staying motivated and keeping active) but they are not required to text in step count each week	
Encourage them to wear pedometer if they find it helpful and to keep recording steps (if finding this helpful).	
Ask if participant has any questions.	

3v c. PROPELS Key Communication Skills Checklist



	1 - POOR	2	3 - EXCELLENT
Educator engages in brief social behaviour (e.g., greetings, personal remarks, social conversation) that is unrelated to the intervention (building and maintaining rapport)	educator engages in little (or no) social conversations, and gets straight into intervention delivery <input type="checkbox"/>	<input type="checkbox"/>	educator engages social conversation which builds and maintain rapport, but leaving sufficient time to deliver the core content <input type="checkbox"/>
Educator has a positive approach and attitude; is explicit but not negative about participant challenges and concerns (e.g. warmth and tone of voice)	educator sounds cold, distant, or unfriendly <input type="checkbox"/>	<input type="checkbox"/>	educator sounds warm, friendly, engaged, helpful, caring and compassionate <input type="checkbox"/>
Educator asks open-ended questions where possible	educator misses many opportunities to ask open-ended questions <input type="checkbox"/>	<input type="checkbox"/>	educator asks open questions at every possible opportunity <input type="checkbox"/>
Educator uses affirmations where possible to recognise and acknowledge participant's strengths	educator misses many opportunities for affirmations <input type="checkbox"/>	<input type="checkbox"/>	educator uses genuine affirmations when opportunities arise <input type="checkbox"/>
Listening Skills:			
Educator uses reflective listening where possible (e.g., seeking to understand the participant's experience, then to confirm it has been understood correctly)	educator does not seek to understand the participant's experiences or reflect it back to them to confirm understanding <input type="checkbox"/>	<input type="checkbox"/>	educator communicates that he/she has tried to understand participants' concerns (by reflecting the concern back to the participant) <input type="checkbox"/>
Educator listens to what participant is saying	educator interrupts participants when they are talking <input type="checkbox"/>	<input type="checkbox"/>	educator does not interrupt; listens to what participant is saying <input type="checkbox"/>
Educator uses summaries at key points during the conversation to bring together what the participant says about a given topic.	educator does not use summaries before moving on to the next key step <input type="checkbox"/>	<input type="checkbox"/>	educator uses short but succinct summaries before moving on to the next key step. <input type="checkbox"/>
Educator allows participants to come up with their own suggestions/solutions rather than telling them what to do	educator tells participants what to do; offers suggestions without letting participants think for themselves <input type="checkbox"/>	<input type="checkbox"/>	educator allows and encourages participant to come up with their own ideas and solutions <input type="checkbox"/>
Educator does not talk most of the time (i.e., participant talks most of the time)	educator talks for most of the phone call (>75%) <input type="checkbox"/>	<input type="checkbox"/>	Participant does most of the talking (>75%) <input type="checkbox"/>

3v d. PROPELS Educator Phone Calls Reflection Sheet



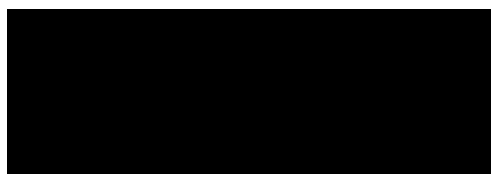
Date of phone call:	Time of phone call:
Identify 3 things that went well during the phone call? 1. 2. 3.	
Any challenges? (if yes, what happened and what are your thoughts as to why this happened)	
What could you have done or said differently?	
How can I improve this?	

Walking Away from Diabetes

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propels
The PRomotion Of Physical activity through structured
Education with differing Levels of ongoing Support
for those with prediabetes (PROPELS): randomised
controlled trial in a diverse multi-ethnic community