



# Physical Activity as a TREATment for Depression

## Physical Activity Facilitator Manual

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# 1 The TREAD Project

## TREAD: Physical Activity as a TREATment for Depression

### 1.1 Background and objectives

Depression is one of the leading reasons for disability in the UK and the third most common reason for consulting a general practitioner. The vast majority of people with depression are treated in primary care, often involving antidepressant medication. Whilst antidepressants have been shown to be clinically effective, many patients and general practitioners (GPs) would like to have access to other forms of treatment which can be used either as an alternative, or in addition to drug therapy, particularly for the management of the more common, less severe forms of depression.

Physical activity has been shown to have positive effects on several aspects of mental well-being. In addition, it is associated with reduced risk of subsequent depression and dementia. There is some evidence that physical activity can be helpful in treating depression and it is recommended in guidelines by both NICE and the Mental Health Foundation as a helpful aspect of treatment. However, the quality of the research has not been high, leaving some question as to the extent of the effect of activity. Furthermore, there have been no robust attempts to evaluate the use of physical activity as part of treatment in the primary care system in the UK.

The TREAD trial is a collaborative venture between the Universities of Bristol and Exeter and draws on expertise from the fields of Primary Care, Psychiatry, Social Medicine, and Exercise & Health Sciences. It runs from August 2006 to January 2011 and is funded as part of their NIHR Health Technology Assessment programme. The aim of the trial is to test whether a support system for physical activity, in addition to usual care, can change the outcome of depression and alter subsequent and future use of antidepressant medication. To achieve this, a randomised controlled trial is being carried out in which an intervention group receives physical activity support in addition to their usual care.

The purpose of this manual is to provide a detailed description of the rationale and protocol for the intervention. Intended readers are physical activity facilitators working on the TREAD project. A more detailed description of the TREAD intervention rationale, theoretical underpinnings, content, and the physical activity facilitator role can be found at Haase, A.M., Taylor, A.H., Fox, K.R., Thorp, H., Lewis, G. (2010). Rationale and development of the physical activity counselling intervention for a pragmatic Trial of Exercise and Depression in the UK (TREAD-UK). *Mental Health and Physical Activity*, 3, 85-91. The contribution of the authors to the manual are as follows: KF, AH and AT provided the main input towards developing the intervention and are listed in alphabetical order. HT and GL also contributed to developing the intervention while GB helped to prepare the report. All authors have commented on the final version.

### 1.2 Research protocol

TREAD is designed as a pragmatic, randomised controlled trial, to which patients recently diagnosed with depression are recruited and randomly allocated to one of

two treatment groups; either the physical activity support intervention plus usual care from their GP (termed throughout this document the 'intervention' group) or simply usual care from their GP (termed the 'control' group).

The trial aims to recruit patients who had been recently diagnosed with a new or first episode of depression via general practice. GPs are asked to identify such patients during their consultation and give them preliminary information about the trial. GPs do not recruit directly into the trial but instead ask for the patient's permission to be contacted by a member of the research team. Participants are recruited and randomised equally between intervention and control groups from the wider Bristol and Exeter areas. Patients who agree to enter the trial are interviewed and assessed for eligibility by a member of the research team, using a standard questionnaire. The primary purpose of this questionnaire is to determine a patient's suitability for inclusion in the trial based on mental health status i.e. whether depressed or not and the severity of their condition. Participation is entirely voluntary and agreeing or declining to take part does not affect a patient's usual care in any way. Anyone who decides to take part is free to withdraw at any time and without giving a reason.

Participant information remains entirely confidential and will not be disclosed to anyone outside the research team without their explicit permission. However, participants' GPs are notified of their patients' inclusion in the trial. As part of the consent process of the trial, participants are asked for their permission for the research team to access their medical records. Anonymity is assured unless there is any indication that a participant has suicidal intentions, whether expressed to a member of the research team or their Physical Activity Facilitator (PAF). In this case, confidentiality may be broken and the participants' GP notified because of concerns about safety.

Research is conducted throughout the trial in order to evaluate the acceptability and perceived benefits of the intervention to participants as well as the acceptability and impact upon healthcare practitioners of providing and being involved in the intervention. There is also an economic analysis to compare the costs and benefits of providing the intervention against the costs and benefits of receiving usual care.

### **1.3 Intervention and the role of PAF**

#### ***Intervention group***

The intervention is offered in addition to usual care and does not interfere in any way with the participants other treatments offered by the GP

The aims of the intervention are different from those of the trial. Whilst the trial looks to the measurement of the overall impact of introducing physical activity into the care package that patients receive from their GP, in terms of changes to their depression or use of anti-depressant medication, the intervention seeks to:

- promote sustained physical activity
- facilitate and promote confidence in decision-making for physical activity
- facilitate increases in perceived competence for physical activity
- provide social support
- provide educational materials where helpful
- provide information on local opportunities for physical activity where helpful

Participants are first asked to attend an appointment with a Physical Activity Facilitator (PAF). The appointment lasts approximately one hour and takes place either at their general practice or their home. During this appointment, the PAF and the patient discuss ways of incorporating more physical activity into the patient's life. The PAF discusses activity options and may provide information on the activities held in the local area. Together, the patient and PAF work towards the identification of acceptable forms and amounts of physical activity and set realistic short- and longer-term goals, suitable for the patient's individual situation. The PAF may also give advice about how best to achieve those goals, such as breaking tasks down to make them more manageable. Participants have two further face-to-face sessions with their PAF over a 6-8 month period and are also provided with up to 10 telephone contacts for support and encouragement.

### ***Usual care group***

Participants in this group continue to be under the usual care of their GP for the management of their depression. Being allocated to this trial group does not interfere with participants' normal daily life or treatment in any way.

From a participants' perspective, the research lasts one year. They are asked to complete some short questionnaires at 4, 8 and 12 months after entering the trial in order to find out whether their depression, attitudes regarding activity and their activity levels have improved or not. In addition, some participants may be invited to wear an activity monitor for a week during the trial to measure physical activity levels. A small number are also asked to provide an interview regarding their experiences.

## **2 Core knowledge and skills**

### **2.1 Depression**

#### ***Definitions***

Depression is a common and debilitating illness. There is now a great deal of agreement about the symptoms that support the diagnosis of depression. In the UK we tend to use the criteria for depression agreed by the WHO as the International Classification of Diseases (10<sup>th</sup> Edition) or ICD-10. As with most medical conditions, each individual tends to have a slightly different combination of symptoms.

There is a continuum of severity between the normal ups and downs of emotional life and the more severe depressions that benefit from treatment. There does not appear to be any qualitative difference between "clinical" depression that meets diagnostic criteria and depression that is below that threshold. People with sub-threshold symptoms are more likely to develop depression and those who only partially respond to treatment are more likely to relapse.

## ICD-10 Depression Definition

In typical depressive episodes the individual usually suffers from depressed mood, loss of interest and enjoyment, and reduced energy leading to increased fatigability and diminished activity. Marked tiredness after only slight effort is common.

Other common symptoms are:

- reduced concentration and attention
- reduced self-esteem and self-confidence
- ideas of guilt and unworthiness
- bleak and pessimistic views of the future
- ideas or acts of self-harm or suicide
- disturbed sleep (occasionally sleeping too much)
- diminished (or increased) appetite

Most people with depression are treated within primary care by their GP. It is common for people to originally present to their doctor with physical complaints such as headaches, tiredness, insomnia or pain. The GP may, at times, have to persuade the patient that they have depression rather than a “physical” condition.

### ***Treatment in the UK***

Most people who receive a diagnosis of depression will be treated with antidepressants. The most common type of antidepressant drug group is the Selective Serotonin Reuptake Inhibitor or SSRI. Serotonin is a neurotransmitter in the brain. However, there are other types of antidepressant medication which can affect other neurotransmitter systems. All antidepressants have side-effects but these are idiosyncratic and if someone cannot tolerate one antidepressant, they may be able to tolerate another. Antidepressants have both a trade name (e.g. Prozac) and a generic name (e.g. fluoxetine).

All antidepressants need to be taken every day for several weeks if they are to work. They are not effective if people just take them on days that they feel particularly unwell. It also takes 2–3 weeks before someone experiences any benefit from treatment. Once someone feels better, continuing to take antidepressants helps to reduce relapse. It is recommended that antidepressants are taken for between 6 and 12 months after recovery.

### **SSRIs** (the trade names are in parentheses):

Citalopram (Cipramil), Fluoxetine (Prozac), Paroxetine (Seroxat), Setraline (Lustral), Fluvoxamine (Faverin)

**Common side effects of SSRIs:** nausea, vomiting, diarrhoea, insomnia

### **Some other antidepressants:**

Reboxetine (Edronax), Mirtazapine (Zispin), Venlafaxine (Efexor)

## 2.2 Physical activity

### ***Physical activity, mental health, and depression***

Depression is commonly seen in primary care, with medication and counselling often the choice of treatment. Although antidepressants can be effective, many people don't respond to treatment or fail to comply with taking medication. Furthermore, some patients prefer not to be medicated and look for alternative approaches. Therefore, additional treatment methods are needed and should be considered, and so there is scope for non-medication approaches in the treatment of depression.

There is much evidence supporting the benefits of physical activity for improved mental well-being such as enhanced mood, reduced anxiety and stress levels, and improved self-perceptions. Physical activity can help people who are not suffering diagnosed mental illness feel better, feel more positive about themselves, and perhaps sleep and cope with their stress levels better. Physical activity and exercise have been linked to improvements in mood and reduction in depressive symptoms in mild to moderately depressed individuals. However, there is a particular challenge in engaging depressed people in physical activity. The symptoms of depression described above indicate that the illness is accompanied by lack of confidence and apathy so that the drive to take on what may be a new and difficult behaviour can be daunting for many.

To date the most commonly used form of physical activity promotion in primary care has been the GP referral for exercise or exercise prescription scheme. There remains an absence of evidence for the effectiveness of these schemes for patients in general and also for patients with depression. Furthermore, they require attendance at a leisure centre, where exercise takes place in group settings. This provides quite a formidable challenge for many depressed patients and so recruitment and retention in such programmes is likely to be low. Thus, there is a need for an alternative supportive approach to facilitating individuals with depression to take up physical activity and ultimately regular exercise.

### ***Physical activity targets***

Physical activity is characterised by frequency (how often), intensity (how hard), time (how long) and also the type or mode of activity (walking, swimming, weight training, or various sports). For most health benefits activity that is at least at a moderate intensity is required for substantial benefit. However, for those who are used to very little activity, increasing levels will produce some improvement in fitness and some aspects of health (mental well-being in particular). Moderate intensity activity is the equivalent of brisk walking and requires getting mildly out of breath and sweating.

There is only limited evidence to indicate the amounts and types of activity that may work for decreasing depressive symptoms. The Department of Health suggest the same recommendations used for the general population are beneficial for the prevention and treatment of depression. These recommendations are that moderate intensity physical activity is achieved for at least 30 minutes on at least 5 days of the week. Activity does not have to be continuous for 30 minutes but can be in shorter 10 minutes bouts throughout the day.

Bouts of moderate intensity activity which last between 20 and 60 minutes are thought to be effective as a treatment for depression, although studies producing these results have focussed on formal exercise programmes. A recent trial on activity indicated that more intensive levels of activity were more successful. Shorter 10-15 minute bouts of exercise may also produce positive changes in mood.

Regardless, less than 30% of the national population engage in the recommended amounts of activity and it is likely that most people with depression will be achieving very low levels and will spend a great deal of time spent sedentary. For the majority, a stepped and supportive approach is therefore required to help them gradually increase their activity levels towards recommended amounts.

### ***Barriers to physical activity***

Although physical activity recommendations may seem easily achieved through lifestyle alterations, to many people they may sound like they are not worthwhile or are unachievable. Participating in exercise or physical activity may be hindered by a number of barriers including the commonly stated beliefs and attitudes listed below:

- *I've never done it*
- *I wasn't good at sports at school*
- *I would feel silly*
- *Other people would make fun of me*
- *It won't help unless it hurts - 'No pain, no gain'*
- *It's sweaty and uncomfortable*
- *I'm too tired*
- *I would rather do something else*
- *It's expensive*
- *I think it will make me feel worse*
- *I don't have anyone to do it with*
- *I don't know where, when or how to start.*
- *I just don't have any time*

Some of these barriers originate from the misconception that in order to be active for health, a person needs to be sporty or athletic. Feelings of inadequacy, can be further compounded in settings such as fitness clubs and swimming pools where the body is on public display. What is required therefore is a redefinition of what valuable physical activity can be. This includes activities that can be incorporated in every day life such as walking the dog, cycling, jogging, gardening, dance, and a diverse range of other activities. The emphasis for depressed people should therefore be on preferences, feasibility and whatever will help them begin to lead more active lives.

## **2.3 Behaviour change theory and practice**

There are several theoretical frameworks that were considered for adoption to underpin the intervention. These included the Health Belief Model, the Theory of Planned Behaviour and the Transtheoretical or Readiness to Change Model. Each of these has valuable elements that can inform practice. However, the best fit for the specific needs of the depressed patient, we feel is Self-Determination Theory (SDT). This has been recently applied successfully in weight loss and exercise settings. The essence of this theory is that motivation and self-esteem are enhanced by increases in feelings of autonomy or personal agency. Autonomous motivation and psychological well-being are facilitated when three innate needs are satisfied; (i) autonomy (being the origin or controller of one's behaviour and its consequences),



(ii) competence (feeling effective and capable in one's environment) and (iii) relatedness (feeling a mutual sense of connectedness with others). Thus, a support system that helps depressed patients feel more physically competent and confident in their ability to make changes to their physical activity and that engenders being part of a supportive network should increase their motivation for physical activity. Research has shown that effective counsellors and leaders are able to create a communication climate that fosters these kinds of feelings by (i) being autonomy-supportive (e.g., engaging patients in decision-making), (ii) providing structure for changes in behaviour (e.g., clear expectations and guidelines) and (iii) being interpersonally involved (e.g., showing empathy). Professionals who use these empowering strategies can have positive effects on motivation, behavioural engagement, and psychological well-being.

However, as with all psychological theories, SDT does not provide all the answers. Social context is also important in facilitating behaviour change. Beliefs about what important others think about exercise and being physically active will contribute to motivation to engage in some activity. Important people in the patient's life may provide both negative and positive support, in varying degrees. Confidence in using physical activity to improve mood may be affected by others' values and behaviours around activity. Patient satisfaction with various dimensions of support (e.g. emotional, informational) will be important to consider for fulfilling their tasks.

Physical activity is also likely to be dependent on availability and accessibility of opportunities. Providing information on local offerings will be important. The nature of the local physical environment in terms of aesthetics, safety and whether or not it offers a culture of physical activity will be important. Financial, family and occupational demands will also impinge on decisions and capacity to be active. These are all important factors to be aware of when working with and facilitating choice in patients.

**For patients with depression, therefore a very specific approach to physical activity is required in order to achieve the overall aim of facilitating sustained increases in patient's physical activity.**

When working with depressed patients, this requires an approach with particular characteristics:

1. **Flexibility.** In contrast to the prescribed exercise approach where a fixed amount of activity based on frequency, intensity and time is pursued, flexibility is required to accommodate patient preference and estimates of what they feel they can achieve. Activity programmes will therefore be unique to each individual.
2. **Opportunity.** Many patients (as with the population as a whole) will have constrained views of what counts as health-enhancing physical activity. Broadening this perspective to the whole range of activities available and locating opportunities in the local community become very important.
3. **Sustainability.** Choosing activities that can be built into routines and become part of lifestyles is important for sustaining longer term behaviour change.
4. **Ownership.** Helping patients see that their own efforts and decision making have led to success helps build activity into personal identities and this in turn can lead to longer term commitment and motivation to sustain the behaviour.

## 2.4 Communicating with patients

In line with the theoretical framework adopted for the intervention, the following are key principles to follow when working with patients:

### **Allowing choice**

- Ensuring that the patient understands the approach/model and giving every opportunity for the patient to feel that it offers a useful way of exploring options.
- Being aware and accepting that not all patients will embrace physical activity after their initial session
- Being aware that any activity will be beneficial and that working towards the government recommended levels of activity is the long term rather than immediate target.

### **Developing rapport**

- Listening to the patient, making sure that the point is understood and that there may be underlying issues behind statements. Ask questions rather than give instructions
- Asking patients how you can help them achieve their plans
- Asking what stopped them achieving goals this week
- Avoiding being judgemental, and asking patients to make assessments of their progress and express their feelings about it.
- Summarizing what the patient has said for confirmation and to increase your own understanding.

### **Making sure the patient understands the rationale**

- Referring back to the patient's list of problems
- Making the link between why they consulted their doctor and the activity programme
- Repeating the rationale and referring back to guiding models

## **2.5 Motivational interviewing**

**Definition of brief motivational interviewing:** a directive, client-centred negotiating style for helping patients explore and resolve ambivalence about exercise (and other health behaviours) (Rollnick, 1992)

Motivational interviewing (MI) is an approach to behaviour change that fits the rationale and philosophy described so far. It is based on the idea that motivation to change behaviour will be enhanced, negotiated and directed by the interpersonal interaction between the patient and facilitator or professional. It is important to understand the philosophy behind motivational interviewing in order to correctly use techniques and work through ambivalence with patients. As a patient-centred approach, MI assists patients in articulating their concerns and arguments about behaviour change. MI is a flexible approach, with a number of strategies to choose from to match the level of readiness to change within each individual. The goal of motivational interviewing is to help patients with their ambivalence towards changing behaviour through a series of techniques.

**Ambivalence:** Conflict between two different actions both having perceived costs and benefits. The main concept used is decision balance, weighing up the pros and cons of remaining inactive as compared to the pros and cons of being active.

**Readiness to change:** Determining where the patient is on a continuum of being ready to change their behaviour is crucial. Readiness to change is an important factor to address in order to negotiate with the patient through from not being prepared to change to the 'already changing' stage. Key questions to ask regarding this are 'How important is it to you to change?' and 'How confident are you in making that change?' These two questions will provide indication of the levels of readiness to change and are also extremely useful tools for you to use as the facilitator to encourage discussion around ambivalence.

### ***Key principles***

**Roll with resistance** – As a facilitator it can be useful to offer new perspectives, but it is important not to impose them on the patient.

**Express empathy** – the key is to **actively** listen to the patient's point of view and accept it even if you don't approve of it.

**Avoid argument** – remember not to 'label' the patient as it encourages defensiveness and resistance from the patient.

**Develop discrepancy** – negotiate with patient to consider the consequences of their health behaviour and develop an awareness of the importance of the consequences.

**Support self-efficacy** – Assist patient through determining their own choices and understanding their own capabilities, pushing the boundaries progressively but only with their permission.

### ***Patients resistant to change: Why?***

There are three main reasons why patients may be resistant to behaviour change. The first reason is that they may feel like they are having their control taken away from them. The right way to deal with this is to emphasise that the patient retains choice and control at all time.

A second reason may be that you as the facilitator have misjudged or misinterpreted the patient's readiness to change, or how important and/or how confident they are in changing. By revisiting these issues, the facilitator will have an opportunity to make a clearer judgment regarding these points.

The third reason may be that you as the facilitator have been a bit too confrontational, meeting force with force. This may occur when discussion around issues that the facilitator may consider straightforward in one instance turns out not to be so straightforward in the patient's view. To manage this, it's best to back off and essentially 'come alongside' the patient, not agreeing with them but changing tack and emphasising their own control and choice in the matter and negotiating the idea of change back into the discussion.

### ***Golden rules of Motivational Interviewing***

- R: Roll with resistance
- E: Express empathy
- A: Avoid argument
- D: Develop discrepancy
- S: Support self-efficacy

## 2.6 Behavioural techniques

### ***Breaking down tasks***

Depressed people often tend to be discouraged by large tasks and any difficulties or problems seem overwhelming. The main strategy to prevent this is to break down large tasks into smaller tasks that are easier. For some people, it might be important to suggest doing a limited number of these tasks during a week. For example, agree to perform steps 1-4 below in the first week.

**For example, someone might suggest playing tennis as an activity. A break down of this task might be as follows:**

1. find, borrow or buy tennis racket
2. find or buy tennis shoes & clothes
3. locate tennis court
4. find out how to book court
5. find someone to play tennis with
6. arrange mutual dates
7. book tennis court
8. re-contact friend with time and place
9. travel to tennis court at prearranged time
10. play tennis

### ***Agreeing achievable goals***

The goals for activity need to be agreed with the patient. It is a collaborative activity. Depressed people often set unrealistic goals that are too ambitious. If someone has not been exercising for some time they might set a target more appropriate for when they were more active in the past. Therefore make sure that you agree a realistic goal, particularly one that is easy to achieve. If people fail to achieve their goals then it can be discouraging.

Be aware that sometimes, people might achieve the goal but still come back and describe it as a disaster. This is because they have added on extra aims that you were not aware of at the time. For example, they might say “I went for a run around the park but had to stop twice”. The original agreed task was to run around the park but on return they have added an extra goal, to carry out the run without stopping. Remind the patient of the original aim and suggest that you include the additional aims in next week’s tasks.

### ***Treating the activity as an experiment***

There are two aspects to the possible psychological benefit from exercise:

1. Enjoyment
2. Sense of achievement

If you treat the exercise as an experiment, you could suggest that the patient rates their expected enjoyment and sense of achievement before they carry out the agreed task. Then complete the same ratings after the task. Quite often, the patient either enjoys or has a greater sense of achievement than he or she expected. However, this is an experiment and everyone is different. It might also help them to choose the kind of things that they get the most benefit from.

### ***Possible discussion topics and questions***

- Lifestyle, stresses, and health in general
- What is a typical day?
- Assessing motivation and confidence for physical activity
- What are the good things and less good things about physical activity?
- Providing information on opportunities
- What are past experiences of physical activity and where would you like to be?
- Modified barrier approach: reasons why do you want to and reasons why not
  - Explore reasons
  - Emphasise personal control and choice
- What kinds of friendships are most rewarding?

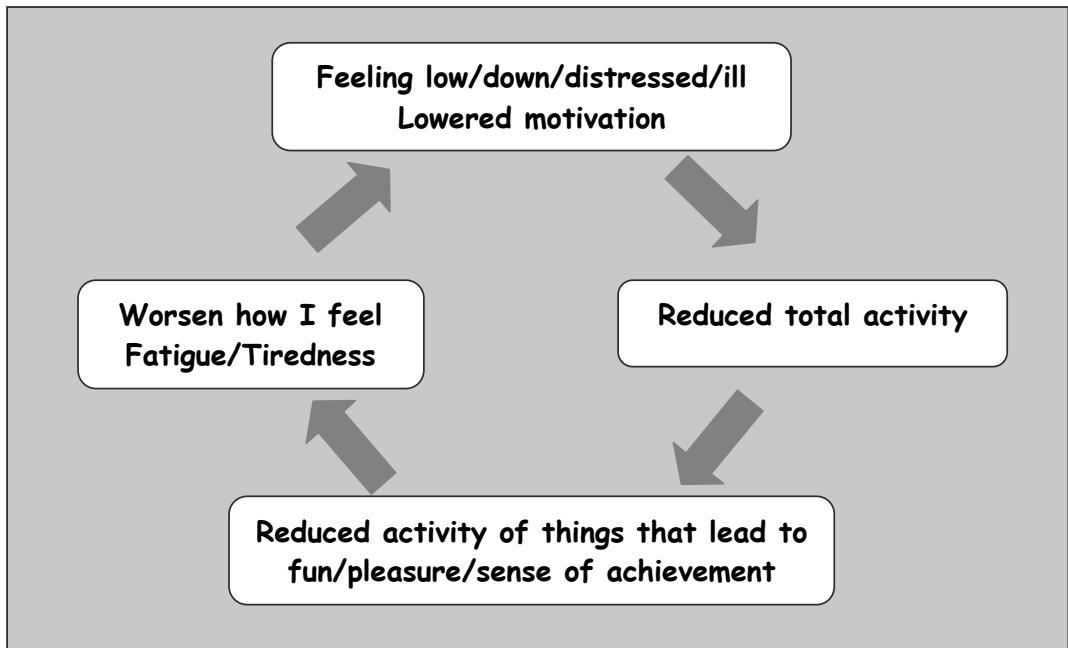
## **3 Delivering the intervention**

The intervention content takes the form of three face to face sessions lasting up to one hour long and up to ten phone calls to be delivered over an 8 month period. There is some degree of flexibility in how these are arranged so that the programme can be tailored to patient needs and preferences. However, key objectives are set out for achievement in early sessions and a common framework for their delivery are written into the structure and content.

The physical activity intervention is primarily based on principles of Self-Determination Theory and the communications strategy is derived from motivational interviewing. These are very useful for assisting the Physical Activity Facilitator. However, the patient may benefit from a model that is much simpler and relatively jargon free. Such a model that has been used previously in therapy setting is the Spiral model of recovery.

### **3.1 Spiral model and the 'Feel Good Factor'**

The aim for the patient is to **reverse inactivity, experience the feel good factor and turn the spiral to an upward path, hence bringing them out of depression**



The benefits of this model are:

- it can be easily understood and identified with
- It can provide a focus for discussion
- experiences from every day life can be described for each element
- physical activity can be interjected as the target behaviour

When using the spiral model:

- Describe to the patient that inactivity can lead to depression which can lead to more inactivity (of any sort)
- Introduce the idea that 'Inactivity can drag you down, and physical activity can pull you up'

Often people associate physical activity with improved mood and 'feeling good'. This 'feel good' factor may be explained in a number of different ways. One explanation involves different body chemicals (serotonin, endorphins, cortisol) being produced when a person is physically active, generating an uplifting or positive mood.

Another explanation is that psychological and social factors such as self-esteem, confidence and social interaction can result from successful physical activity experiences. This in turn can play a significant role influencing whether or not individuals move toward taking up more physical activity. People are often motivated for different reasons; weight loss, body dissatisfaction, health improvements and social networking are popular examples. All of these motivations can potentially have an impact on improved mood and feeling good.

The 'feel good' factor may also be connected to the idea of distraction. The 'Distraction' approach is understood to be where physical activity distracts an individual from depressive thoughts and re-focuses their attention on something other than their current situation. Often, getting people to go for a short walk, thus, changing the environment and getting fresh air, are considered ways of using physical activity to distract an individual. This also has benefits for the depressed individual's way of thinking, as they frequently worry over how bad they are feeling and the situation they are experiencing. Incorporating physical activity into their day can distract these thoughts and potentially improve mood.

So the spiral model can provide a graphic example of how patients might think of their depression, how physical activity might fit into recovery and how they can use it to help build their lives back up to normality.

## 3.2 Targets of the intervention

It is critical that a consistent and common content is offered and delivered by Physical Activity Facilitators in a style that fits with the principles of Self-Determination Theory and Motivational Interviewing. If there is consistency, then at least we will know what has been tested by the research part of TREAD. For this reason PAFs will be asked to record at least some of their sessions so that we can check the degree to which these principles are adhered to. However, one of the principles is that there is sufficient flexibility in the programme to allow the patient, through their preferences, choices, and strengths to drive their own change.

Although the overall aim of the intervention is to increase activity, SDT suggests the process by which it is best achieved is to satisfy the needs of competence, autonomy and relatedness.

**Perceived competence.** This is the belief in ability in a specific domain. Relevant to a physical activity programme are perceptions of physical competence. This may mean confidence in fitness attributes, strength, sports or other physical skills. It may also mean confidence in body appearance and being able to cope in settings where the body and physical capacities might be judged by others (as in centre-based exercise classes). It could also be extended to confidence in the ability to change behaviours such as increasing activity.

**Autonomy and self-determination.** This is the feeling that you are in charge of your own destiny and the agent of change. Quite often people feel controlled by others or the circumstances in which they find themselves. In the case of depressed patients, this may have developed into a state of helplessness. Through short and incremental goal setting and experiencing small successes that are attributed by the patient to their own efforts, then autonomy should grow. Physical activity may be a strong vehicle for some patients to achieve this.

**Relatedness.** This is about feelings of being part of larger social networks. The opposite is sense of isolation and loneliness. Physical activity can help by stimulating patients to get outside, feel part of a neighbourhood or community, and join other social groups. The PAF role in itself provides a supportive role for this.

The programme content and the style of delivery of the PAF reflect the support required for helping patients have positive experiences regarding these needs.

### ***Negotiating timeframe of session and contacts***

The timeframe may be different for each individual. Initially, sessions 1-3 will most likely occur within the first three week period. Subsequent phone calls and the last face-to-face session should not occur in consecutive weeks but over a period of 6-8 months. However, either the PAF or patient may sense that more contact is required earlier on in the intervention while new patterns are developing. There may be a need for some to stimulate more contact later in the programme when motivation might be fading or some other challenge has emerged making continuation more difficult. Others may be doing so well, that contact is less important in the later stages. There is always scope to change the plan of action but of course this needs to be as a result of discussions with the patient.

### ***Eliciting and exploring expectations***

It is important to stress to the patient that the process is **developmental** and that your role is to facilitate the emergence of skills and behaviours that other people have found useful in the past. The patient role is to identify goals and apply effort to making progress. Emphasise the collaboration principle, i.e. the process of working together to examine and explore activity and possible change. Achieving the balance between making suggestions and allowing ideas to emerge from the patient can be tricky. However, in line with the principles of motivational interviewing, it is critical to allow the patient to drive decisions and negotiations. An early target therefore is to explore patient expectations, and guiding them towards realistic goals.

Questions to ask:

- What are your expectations of this programme?
- What would be a good starting point?
- What would make you feel successful?
- Do you think this is a good idea?

### ***Being aware of key issues***

People with depression often have many challenges in their lives, some of which may be the underlying cause of the depression. Depression can accompany a wide range of life events from bereavement, being made redundant, breakdown of relationships, injury in athletes, accidents, other illnesses. PAFs need to be aware that many patients will be experiencing these key concerns. An empathetic ear is required, however, some patients need to be reminded of the role of the programme and the PAF and its focus on increasing physical activity. PAFs are not equipped to be counsellors for underlying contributors to depression.

## **3.3 Physical activity progression**

The overall physical activity target is for patients in the long term to achieve national recommendations for 30 minutes of moderate intensity activity on at least five days a week. This captures the need for sustainability. Because this target is achieved by a minority of the population, with the difficulties that depression brings, it is ambitious to expect the majority of patients to succeed in reaching these amounts. The focus of the intervention is therefore on **increases** in physical activity and improved fitness and addressing all the psychological and behavioural challenges that this brings.



The principles of **relative dose and progression** are important ones. A less fit person may not be able to achieve the recommended physical dose initially, but may work towards and achieve it over time. Also, this **progression may not be linear**, particularly with depressed patients. There may be days or weeks that provide stronger barriers (e.g. lack of sleep and fatigue, feeling worthless) to physical activity.

It is therefore not appropriate to prescribe a specific dose of activity that will be right for the individual patient as this will not only depend on existing fitness levels but also past experiences of exercise, the symptoms of depression being experienced, life events, and the opportunities on offer for each particular patient.

## 4 Session by session

### Overall Plan of Contact with Patients:

**Session 1:** One hour session

**Session 2/3:** 2 phone calls

**Session 4:** 30-45 min face to face

**Session 5-10:** 5/6 phone calls

**Session 11-13:** 30 min face to face & 2 phone calls

It is important to remember that all these sessions are flexible depending upon patient needs. There may be fewer phone sessions than outlined in the plan below. The first four sessions are also likely to involve discussion of barriers for physical activity but this is likely to be in relation to introducing physical activity and initial choice of type of activity. Working through barriers in session 5/6 is more likely to be related to specific barriers the patient experiences attempting to take part in the activity they have chosen in earlier sessions.

The exit strategy of the facilitator should be considered and worked into the sessions from approximately session 7, as the facilitator needs to prepare the patient to continue with physical activity independently, once the sessions have come to an end. As the patient moves towards routine and continuing activity it will be important for them to start thinking about triggers or cues to look out for in the future, to help them recognise when their activity levels are decreasing. This will allow them to think through ways of maintaining their activity levels when they are not regularly seeing the facilitator.

Each session can cover the following topics:

### Agenda

It is important to set an agenda at the beginning of each session. This encourages the patient and facilitator to use the time effectively. It also encourages the patient to bring things to the session and work in between sessions. It can be simply a few comments at the beginning of the session either by phone or in person.

### **Reviewing Agreed Tasks**

It is essential to review the previously agreed tasks and goals that the patient has carried out. This will provide information as to where the facilitator can assist the patient in problem solving to encourage more physical activity.

### **Feedback**

What does the patient think of using physical activity and the model? Are the important problems being addressed from the patient's perspective? What are the useful things in the session? What are the not so useful? Are there other approaches that would be useful? Has the facilitator said anything that has upset/offended the patient?

### **Setting and Revising Agreed Tasks/Goals**

Always allow enough time to think of relevant tasks and time to come to agreement, explain to the patient and establish that the patient agrees it is sensible. Encourage the patient to think of and set his or her own tasks/goals.

### **Main purposes session by session:**

**Session 1:** Assessment and introduction (one hour in person)

**Session 2:** Commitment, planning and goal setting (phone call)

**Session 3:** Discussion of progress, outcomes and barriers. Goal setting (phone call)

**Session 4:** Revision of progress and discussion of medium-long term goals (30-45 min in person)

**Session 5/6:** Discussion of progress, working through barriers and alternatives (phone call)

**Session 7/8:** Moving towards routine. Discussion of maintenance strategies. (phone call)

**Session 9/10:** Management of barriers and continuing activity (phone call)

**Session 11-13: Final face-to-face contact and 2 phone calls:** Revision of progress, PA levels and general wellbeing. Consolidation of maintenance strategies. (30-45 min in person). Prepare exit strategies for end of intervention.

## 4.1 Session 1: First face-to-face contact

### Session 1: Assessment and introduction

#### Time: One hour face-to-face person contact

The first session will approach from a psychological orientation

#### Aims/Objectives

1. Establish rapport with patient
2. Explain approach and how physical activity can help with their problems
3. Ensure patient's understanding of PA
4. Plan PA strategy and work through possibilities
5. Plan the communication strategy

#### 1. Session content

- Explain the approach and how the intervention works, including the role of the PAF and the session outline.
- Discuss how the depression is affecting their daily lives.
- Discuss their current level of activity and other lifestyle behaviours
- Identify any previous experience of physical activity (use to explore later; what they enjoy, what previously worked, why and how they did activity)
- Discuss specific problems related to the depression (e.g. lack of energy, sleeping problems) and how this affects them in their day to day lives. Resist imposing your own opinions but prompt with questions if you feel the patient has left anything out.

#### 2. Introduce the Spiral model

- Describe approach to understanding depression (show spiral model from page 7/Appendix A). Use the sheet to explain how activity levels can go down and how this can lead to a worsening of depression symptoms. Explain how increasing physical activity can help to manage and reduce depression symptoms.
- Discuss how the problems the patient mentioned earlier link with the spiral model and see if this makes sense to the patient.
- Once the patient understands the usefulness of PA in relation to the model move on to the next steps.
- Check the patient agrees with the model
- What is the patient's understanding of the usefulness of PA?
- What do they think of PA?
- What do they think of planning out goals and tasks each week?
- Is there anything that you haven't discussed that is important to them? (Put it on to the agenda for next week)
- Need to guide the patient towards identifying with PA (if not done so before) or reinitiate mental association with PA.

#### 3. Assess basics

- What PA have they done in the past and what do they do now?
- How do they feel about their current level of PA compared to how this was before the onset of the depression.
- Preference for sedentary behaviours
- Preference for physical activity

- Identify barriers (MI)
- Examine possible options for doing PA – at home, with group, getting support from family and/or friends etc

Discuss with the patient the options for incorporating PA in to their life. Find out if there is anything they would like to do or something they have enjoyed in the past. Select where able to incorporate PA for immediate intervention. This has to be important to the patient but also reasonably amenable to flexible changes. Make sure you do not pick something the patient doesn't think is that important. Advantages and disadvantages – this is where MI might come in as well: How confident is the patient that they can change? How important is change for the patient?

#### **4. Plan**

Leave enough time to agree tasks/goals. Patient is to plan initial steps to carry out focussing on initial manageable goals, but with the understanding that the plan is to progress over a period of time not just a couple of weeks. Make these tasks/goals highly specific and something it is difficult or impossible to “fail” at. The patient is more likely to succeed if the tasks are realistic and achievable. This will also help them identify where there may be practical problems and think of ways to deal with this if possible or alter the tasks if necessary. Identify where extra support from others may be needed if applicable.

Give the rationale for the worksheets, e.g. the Activity Planning, Tracking and Goal Table (Appendix A) helps patients to identify the good and bad times of the week, and things that make the patient feel better or worse. It also helps them to track their progress. Helps patient to be more aware of how he/she feels as a prelude to finding out if physical activity does help to lift their mood. Planning physical activity will help patient to think specifically about what they are going to do and when. Anticipate the difficulties – make sure feedback is received about how patient feels about completing worksheets and the agreed tasks. Consider referring to the compendium of activities if the patient is asking for information about different physical activity options and possibilities in their area.

Explain how the sessions will progress, including face to face, telephone and possibly email and text communication where appropriate. Discuss the patient's preferred mode of contact and their availability. Explain that the phone calls should be arranged for a time the patient can set aside to talk in a private place, ideally without distraction.

Feedback Remember to ask the patient how they feel about the issues discussed. Ask the patient about how important they see the changes you have been discussing and how confident they are in the goals that have been set. Check throughout the session that the patient understands and make sure the patient is given the opportunity to discuss anything else they feel may need covering or discussing. If time is an issue, this can be put on the agenda for the next session.

#### **Worksheets for patients**

See Appendix A for worksheets and instructions:

- 1 Activity Planning, Tracking and Goal Table
- 2 Pros and Cons of Change Table
- 3 Advantages and Disadvantages of Different Activities Table
- 4 The Spiral Model
- 5 Activity Continuum

Consider how much you are sending home with patient. The key is to NOT overload them with work as this will not encourage participation. Negotiate with patient how they feel about completing homework and how much is too much. This will be different for each individual.

***PAF to send out extra worksheets later on if negotiated through phone calls...***

### **Information for PAF**

Before the session ensure appropriate information has been received from the Trial Coordinator. Make sure there is a plan for conducting the initial session with the patient. Remember to check to make sure covered all issues.

Complete the **post session summary sheet (Appendix B)** to record main issues covered during session. This is important to help remember important points for future sessions. It will also be helpful to record plans for future contact and availability. Also complete the **contact monitoring form (Appendix B)** to ensure that a record is kept how many sessions the patient attends (either on the phone or in person) and the **PAF reflective worksheet (Appendix B)**, which allows the PAF to reflect on how they are supporting the patient's sense of control/choice, competence and relatedness.

### **Database**

As soon as the PAF receives the patient paperwork or after the first session complete the patient details form on the database.

After the first session complete the recording consent form 1 and record the session on the contact monitoring form and session monitoring form.

After every contact (including sessions, texts, unanswered phone calls etc) complete the:

Contact monitoring form 1 (when this is complete, move on to contact monitoring form 2, then 3)

After every session: Complete the session monitoring form.

## **4.2 Sessions 2 & 3: Telephone contact**

**Session 2: Commitment, planning and goal setting  
and**

**Session 3: Discussion of progress, outcomes and barriers**

**Time: Phone Calls (10-20 minutes)**

Second session will focus on facilitating behavioural change

### **Aims/Objectives of sessions**

1. Facilitating PA experience
2. Assess progress with goals set at last session
3. Revise strategy and set some more goals to work towards

### **Session content**

#### **1. Agenda**

- What to go through in discussion

- Ask about important issues patient has

## 2. Review progress

- Behavioural changes – worksheets, pedometer use
- Use of worksheets to generate discussion on physical activity patterns and related thoughts, good and bad days.
- Review any goals from the previous week and use these to discuss benefits and barriers:  
If they did complete the goal or activity planned then explore how they felt about this, how did they find it? What were the benefits or positive effects they experienced from doing this?  
Talk with the patient about what things they found difficult about completing this goal or activity. This is particularly useful if the patient did not complete a goal or do PA as planned. What made it particularly difficult? e.g. practical/emotional/something else.
- Changes in emotions and thoughts around PA

## 3. Revise strategy and plan

- From review of progress and discussion of worksheets look at where activity is fitting in – negotiate any changes looking at the pros and cons of activities they have been trying and of any future tasks

### Worksheets for session 2/3 for patients

Encourage patients to use worksheets to plan their activity and to think how completing this activity will affect the way they feel as well as monitoring the actual levels of energy and achievement from any physical activity.

### Information for PAF

Remember to look through the last session summary sheet and plan the areas/issues to be covered in the current session. Again complete a **post session summary sheet (Appendix B)** to record main issues covered during session. Also continue to complete the **contact monitoring form (Appendix B)** and the **PAF reflective worksheet (Appendix B)** to ensure that a record is kept how many sessions the patient attends (either on the phone or in person) and when. Complete the session details on the database.

## 4.3 Session 4: Second face-to-face contact

### Session 4: Revision of progress and discussion of medium-long term goals

#### Session content

##### 1. Agenda

- What to go through in discussion
- Ask about important issues patient has

##### 2. Review progress

- Behavioural changes – worksheets, pedometer use
- Use of worksheets to generate discussion on physical activity progress and continue to explore patients thoughts re: preferences, pros and cons,
- Review any goals from the previous week and use these to discuss benefits and barriers:

If they did complete the goal or activity planned then explore how they felt about this, how did they find it? What were the benefits or positive effects they experienced from doing this?

Talk with the patient about what things they found difficult about completing this goal or activity. This is particularly useful if the patient did not complete a goal or do PA as planned. What made it particularly difficult? e.g. practical/emotional/something else.

- Changes in emotions and thoughts around PA

### **3. Revise strategy and plan**

- Go through forms and change if necessary
- Patient to set physical activity plan with identified specifics, identify necessary actions and support
- Use the discussion of previous goals to help with future planning. Hopefully future goals will come from previous experiences. If not try to encourage experiences to feed into planning

### **Worksheets for session 4 for patients**

Continue to encourage patients to use worksheets to plan activities and set achievable goals as well as monitor emotions and thoughts around PA.

### **Information for PAF**

Remember to look through the last session summary sheet and plan the areas/issues to be covered in the current session. Again complete a **post session summary sheet (Appendix B)** to record main issues covered during session. Also continue to complete the **contact monitoring form (Appendix B)** and the **PAF reflective worksheet (Appendix B)** to ensure that a record is kept how many sessions the patient attends (either on the phone or in person) and when.

## **4.4 Sessions 5 to 10: Telephone contact**

### **Sessions 5-10**

**It is important to remember that these sessions are flexible depending upon patient needs**

**Time: Phone Calls (10-20 minutes)**

**The phone calls are likely to cover 3 stages:**

Stage 1: Discussion of progress and changes in wellbeing

Stage 2: Management of barriers and continuing activity

Stage 3: Goal setting

From session 7 onwards: Moving towards routine

#### **Worksheets for patients**

Patients can continue to use worksheets throughout these sessions. They should be helpful for remembering and monitoring PA goals as well as aiding discussion about progress and problems

#### **Information for PAF**

Remember to continue to use the previous summary sheets for planning and to complete a summary sheet after each session. Also continue to add information about the dates and duration of sessions attended by the patient on the contact monitoring form. (Appendix III)

### **Each phone call should be structured to cover the following areas:**

- Review goals from previous week – what PA they planned to do.
- Go through worksheets to discuss what PA actually completed – in order to talk about benefits & problems with PA.
- Move onto discussion of benefits/barriers:  
If did not do PA as planned what made it particularly difficult?  
e.g. practical/emotional/something else.

If completed the activity – explore how they felt about this, how did they find it? What were the benefits or positive effects they experienced from doing this?

- Link this to next week or so. Hopefully future goals will come from previous experiences. If not try to encourage experiences to feed into planning.

### **Worksheets for patients**

Patients can continue to use worksheets throughout these sessions. They should be helpful for remembering and monitoring PA goals as well as aiding discussion about progress and problems

### **Information for PAF**

Remember to continue to use the previous summary sheets for planning and to complete a summary sheet after each session. Also continue to add information about the dates and duration of sessions attended by the patient on the contact monitoring form. (Appendix B)

## **Session 11**

### **Time: Phone Call (10-20 minutes)**

After final face-to-face contact session; 1-2 more phone calls with timing negotiated by patient and PAF

Discussion about triggers or cues to recognise changes in activity and how to manage and modify strategies to keep going with physical activity.



## 4.5 Session 11-13: Final face-to-face contact

### Session 11-13 – final face-to-face contact session: Reinforcing activity and revision

**Time: 30 minute face-to-face person contact**

Most likely to be session 11 but will depend on number of earlier phone sessions.

Exit strategy discussion including:

Triggers to identify when activity is decreasing

Strategies to help maintain activity, particularly in response to above triggers

Plan for conducting remaining phone sessions (e.g. review progress in becoming more active, set further goals, seek other opportunities for physical activity, initiate referral to facility/community-based exercise).

## 4.6 Risk and issues for referral

One of the relatively common symptoms in depression is to think that life is not worth living and people often think about self-harm and may less commonly take overdoses or otherwise harm themselves. As a PAF, you need not discuss self-harm with the patient. It is worth being aware that many people have suicidal thoughts but do not have any intention of acting on these. However, you should refer them back to their GP if you have any concerns. There is a suicide policy at Appendix C.

### **When to advise patients to contact their GP**

#### **Not taking antidepressants as prescribed:**

It is not the PAFs role to check that a patient is taking antidepressant medication as prescribed. However if you find out in your sessions that a patient is not taking an antidepressant as prescribed you should advise them to consult their GP. There might be a different antidepressant they would tolerate or different ways to help them with the side-effects.

#### **Suicidal thoughts or plans:**

Make sure that the patients discuss any suicidal thoughts or plans with their doctor. See the suicide policy at Appendix 3. It is important that you read and understand this before you see any patients.

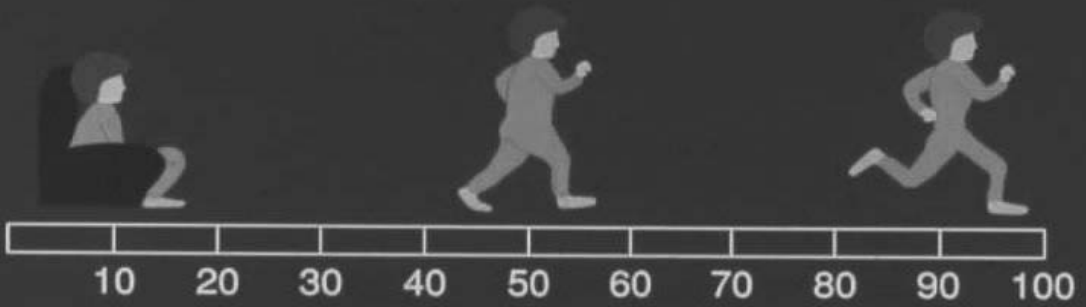
#### **Not getting better or worsening:**

Ask patient to consult their GP if they are not improving after 4-6 weeks or if they worsen.

## Appendix A Worksheets for patients

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# The Activity Continuum



Routine and lifestyle activity points combined



**ACTIVITY PLANNING TRACKING & GOAL TABLE**

Week Beginning:

	Mon	Tue	Wed	Thurs	Fri	Sat	Sun
<b>Planned Activity/ Goals</b>							
<b>Expected Achievement 0-10</b>							
<b>Expected Energy 0-10</b>							
<b>Expected Feeling 0-10</b>							
<b>Actual Activity</b>							
<b>Actual Achievement 0-10</b>							
<b>Actual Energy 0-10</b>							
<b>Actual Feeling 0-10</b>							

**Pros and Cons of Change Table**

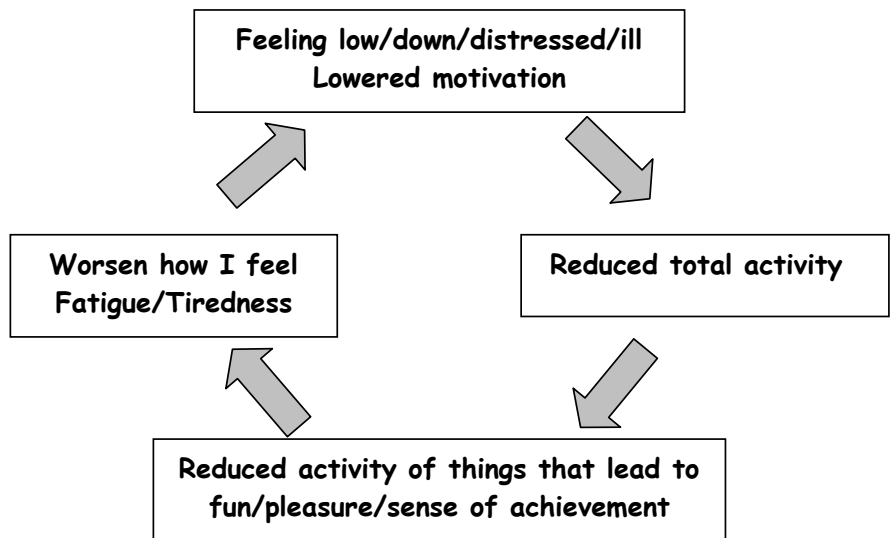
This table can be used to help people identify pros and cons (expectations) for staying the same and changing activity levels (as planned in goal table). This can be completed during the sessions as well as thought about and added to at home.

	<b>Advantages</b>	<b>Disadvantages</b>
<b>Remaining at same level of physical activity</b>		
<b>Reducing sedentary behaviour and increasing level of physical activity</b>		

**Advantages and Disadvantages of Different Activities Table**

Activity	Advantages	Disadvantages/Barriers	Solutions

## REDUCED ACTIVITY IN DEPRESSION



## **5 Appendix B Worksheets for Physical Activity Facilitators**





# PAF Reflective Worksheet

Patient ID

<b>Session</b> (add in if in person or by phone)	<b>Control/Choice</b> (Working with them to explore options and preferences)	<b>Competence</b> (What did you discuss to help them with their confidence?)	<b>Relatedness</b> (Did you ask about social support and how they feel about fitting in with others?)
Session 1			
Session 2			
Session 3			
Session 4			
Session 5			
	<b>Control/Choice</b>	<b>Competence</b>	<b>Relatedness</b>
Session 6			

Session 7			
Session 8			
Session 9			
Session 10			
Session 11			
Session 12			
Session 13			

ID No:

**Post Session Summary Sheet – Session One**

**Date of Session:**

**Session Location:**

**Session Start Time:**

**Session End Time:**

**Length:**

**6 History**

*When diagnosed with depression:*

*Depression Medication:*

*Heart disease:*

*Info on lifestyle behaviours:*

*Any other info or medications:*

**7 Depression Information**

*Current coping strategies:*

*Problems related to the depression:*

**8 Other relevant notes e.g. – typical day, work, social support etc**

8.1 Physical Activity Information

**Past PA:**

***Their thoughts about own cardiovascular fitness:***

***What activity they currently do:***

***What they think they may enjoy:***

***Barriers/pros/cons that concern them:***

8.2 Goals/plans for time in-between sessions

8.3

8.4 Reflection
8.5
<b>Notes about patient availability for appointments and phone calls</b>
<b>Things for PAF to do before next session:</b>
<b>Arrangements for next session:</b>

**Session Planning Sheet**

<b>Session No.....</b>	<b>Date:</b>
<b>Date of last session:</b>	
<b>Goals set at last session:</b>	
<b>Other things to discuss:</b>	

<b>Strategies to try for next week:</b>
---

ID No:
--------

<b>1 Post Session Summary Sheet – Session No. ....</b>
--

<b>Date:</b>		
<b>Session Location (mobile or landline etc):</b>		
<b>Session Start Time:</b>	<b>Session End Time:</b>	<b>Length:</b>

<b>9 Patient Self Reported Physical Activity</b>

<b>10 Patient Self Reported Well Being</b>

**11 Goals/plans for next few weeks in-between sessions**

**Other Information**

**Things for PAF to do before next session:**

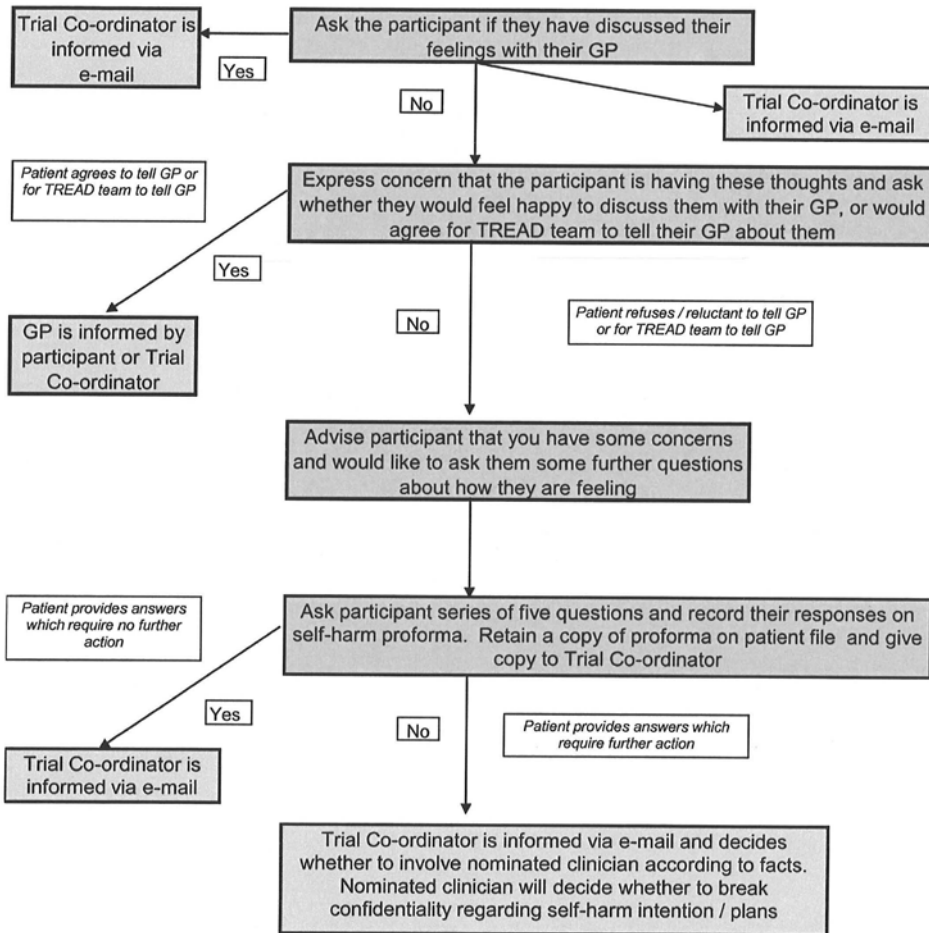
**Arrangements for next session:**



# Appendix C Self harm protocols

## Self-harm protocol for PAFs in TREAD

If at any time, a participant expresses intent or plans to self-harm to a Physical Activity Facilitator (in the course of their face-to-face or telephone sessions) then the Physical Activity Facilitator should invoke the following protocol:



## Self-harm / suicide questions for PAFs in TREAD

	-				-				
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There may be circumstances when a participant tells you about intent to / plans of self-harm or suicide or triggers other safety concerns. In such cases, the following questions should be used as part of the self-harm protocol. Please record details of patient's responses to each question in the relevant space.

*"Sometimes when a person feels down or depressed they might think of harming themselves or feel that life isn't worth living. Others may not feel like this at all. You've indicated some things that make me concerned and I'd like to ask you some questions to check how you have been feeling recently... If I read out each question and all the possible answers, please can you tell me which answer is most appropriate for you. Remember that all these questions relate to how you have felt in the last seven days."*

12 During the last seven days...

1) Have you felt hopeless at all, for instance about your future?

<sub>1</sub> **no**

<sub>2</sub> **yes, I have felt hopeless sometimes**

2) Have you felt that life isn't worth living?

<sub>1</sub> **no** —————▶ **end questions**

<sub>2</sub> **sometimes**

<sub>3</sub> **always**

3) Have you thought of harming or killing yourself?

<sub>1</sub> **no** —————▶ **end questions**

<sub>2</sub> **yes, but I would never commit suicide** —————▶ **go to question 5**

<sub>3</sub> **yes**

4) Have you thought about a way in which you might harm or kill yourself?

<sub>1</sub> **no** —————▶ **go to question 5**

<sub>2</sub> **yes**

5) Have you talked to your doctor about these thoughts of harming or killing yourself?

<sub>1</sub> **yes** —————▶ **end questions**

<sub>2</sub> **no, but I have talked to other people** —————▶ **invoke protocol**

<sub>3</sub> **no** —————▶ **invoke protocol**

.....  
name of PAF    date/signature

If a patient has not talked to a doctor about their thoughts and intentions, then you should continue with the self-harm protocol as follows:

“I am concerned that you are having thoughts of harming yourself. Since this is a very serious matter it is important that you talk to your doctor about these thoughts and I would like to speak to a colleague about helping you to do this”.

*Please inform the Trial Co-ordinator about the situation immediately and they will contact one of the designated clinicians to arrange contact with the patient.*

notified clinicians

**Contact details of study clinicians**

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