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PRAGMATIC RANDOMISED CONTROLLED TRIAL OF A PREFERRED INTENSITY EXERCISE PROGRAMME TO IMPROVE WELLBEING OUTCOMES OF WOMEN LIVING WITH DEPRESSION.

REPORT PREPARED FOR THE BURDETT TRUST FOR NURSING

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BACKGROUND

THE LINK BETWEEN PHYSICAL AND MENTAL ILLNESS

Health is 'a state of complete physical, mental, and social well-being and not merely the absence of disease, or infirmity' (World Health Organisation, 2007). Within the notion of global wellbeing, there are physical, psychological and social constructs, and between them is a complex interplay (Mentality 2003, MHF 2006, DoH 2006).

People with mental health problems are more likely to experience physical ill health than the rest of the population, they have high levels of physical morbidity and mortality (Phelan, Stradins et al. 2001; Nocon 2004, NIMHE/Mentality 2004). This is an enduring theme in the literature base and although government policy and initiatives, and initiatives from national independent organizations seek to improve the situation, as yet little or no improvement is evident in the literature, or to the service users (Bradshaw 2005, Owen & Khalil 2006). For both morbidity and mortality the causes and outcomes are complex, and a range of variables contribute (Robson and Gray 2007), some originating from the patient, such as social deprivation and lifestyle choices; some originating within the care sector, such as side effects of psychiatric medication, needs being unmet, and insufficient practitioner training in meeting physical health needs for this group.

Depression in particular impacts range of physical health outcomes; it is associated with asthma, arthritis and diabetes (Turner 2000), is a risk factor for stroke (Jonas 2000, Ostir 2001) and increases the risk of heart disease by four times (Hippisley-Cox 1998).

WHY IS THE PHYSICAL HEALTH OF THE MENTALLY ILL SO POOR?

Addressing the poor physical health of mental health service users has been identified as a national priority (Department of Health 1999), however service users report that once they have a psychiatric diagnosis their physical health needs are disregarded (Sayce 2000). The evidence supports this claim (Brugha 1989, Gournay 1996, Phelan 2001). Monitoring of physical health of the mentally ill is poor (Burns & Cohen 1998, Paton et al 2004, Greening 2005), despite a number of guidelines to inform practice (National Institute of Health and Clinical Excellence (NICE) 2002, Marder et al 2004), and provision of health education/promotion by community practitioners is 'generally unsatisfactory' (Gournay 1996). Physical health care is not necessarily a priority by mental health practitioners (Phelan 2001). Another contributing factor to unmet physical health care need is the way in which our health services are organised, which has led to practitioners skilled at treating one but not the other (Knutsen and Du Rand 1991, Gray 1999, Nash 2005), this is despite their intrinsic inseparability, underlined by the WHO definition of health. Whilst a growing body of research has focused on the physical health problems of adults with mental illness; less is known about acceptable and appropriate practice regarding the provision of lifestyle interventions to this group (Bradshaw 2005).

THE HEALTH BENEFITS OF PHYSICAL ACTIVITY

There is consistent evidence that physical activity is beneficial across a range of physiological, psychological, and social outcomes that comprise global well-being. In addition, regular exercise improves musculoskeletal health and is associated with reduced risk of premature death and of many life-threatening illnesses such as coronary heart disease, stroke, diabetes and cancer (Thompson 1994, DoH 2004). Exercise can also help people to function better through alleviation of stress and improved sleep (Kubitz et al 1996, Youngstedt et al 1997, Sherill et al 1998), improved mood (Biddle 2000) and self-perception (Sonstroem 1996, Spence 1997, Fox 2000), all of which can alleviate negative affect in a person experiencing a mood disorder (Van de Vliet 2002). Exercise can reduce the risk of suffering clinical depression

(Paffenberger et al 1994, Dunn 2001, DoH 2004). Ideally people need to exercise with sufficient intensity for 20-30 minutes three to five times a week to experience health benefits, though this can be split into ten minute segments (Ekkekakis et al 2000, British Heart Foundation 2003, Callaghan 2004, DoH 2004). Benefits are observed regardless of age or socioeconomic status (DoH 2004).

THE BENEFITS OF PHYSICAL ACTIVITY TO THE MENTALLY ILL

Encouraging regular exercise represents an opportunity to tackle many of the inter-related health problems facing individuals with a mental disorder, such as low self-esteem, obesity, elevated blood pressure, with knock-on effects, for lowering the risk of stroke (DoH 2004). In addition to improving general health and wellbeing, exercise has been shown to have beneficial effects on specific mental illness outcomes. Physical exercise has been shown to be effective as a treatment of mild, moderate and severe clinical depression, and can be as effective as psychotherapy or medication in the long term (Byrne & Byrne 1993, Scully et al 1998, Craft 1998, Blumenthal 1999, Biddle 2000, Mutrie 2000, Lawlor & Hopker 2001, DoH 2004, MHF 2004). In 2000, Biddle et al concluded that 'overall, the evidence is strong enough for us to conclude that there is support for a causal link between physical activity and reduced clinically defined depression', Daley agreed in 2002, as did Craft and Perna in 2004. In the face of the growing body of evidence, The English Department of Health's Chief Medical Officer's 2004 report also concurred that 'physical activity is effective in the treatment of clinical depression' and the 2004 white paper 'Choosing health' concluded that regular physical activity reduces the risk of depression and has positive mental health benefits such as enhanced mood and self-esteem. On the basis of a systematic review of the effect of exercise on depression as measured by Beck Depression Inventory (BDI) scores, Lawlor and Hopker (2001) reported that exercise produced a large decrease in depression symptoms (effect size = 1.1) when compared with no treatment. Mutrie (2002) points out, Lawlor and Hopker offer compelling evidence for the benefits of exercise in depression and unlike drug therapy, exercise has few negative side effects.

These benefits are now recognized in official national guidance on health care, and in particular for depressed individuals, for example, NICE (2004) recommended that sufferers of mild depression of all ages are advised of the benefits of participating in an exercise programme of a moderate level three times a week for 10-12 weeks. Mental health organizations also now recommend exercise as a treatment option for mild to moderate depression, in 'Up and Running' (2004) the Mental Health Foundation review the evidence and present a strong case for exercise referral as 'inexpensive, effective, and having coincidental benefits'.

EXERCISE INTERVENTIONS FOR THE MENTALLY ILL

Despite the fact that consultation rates are three to four times higher than for the general population (Seymour 2003), people with mental illness are less likely to be offered health promotion interventions, or exercise prescriptions (Brown 1999, Burns and Cohen 1998, Cohen and Hove 2001, Friedli and Dardis 2002). Participants in one scoping study felt that their physical health isn't taken seriously as a direct result of their mental health status (Owen & Khalil 2006). Evidence shows that health promotion measures need to be carefully targeted to this group 'health promotion information rarely makes clear its importance and relevance to people with severe mental illness' (Mentality 2003), availability of appropriate, targeted resources is scant (Sherr 1998), and service users have noted this lack, and feel that health promotion campaigns are 'not for us' (Freidli 2002). In 2004, the Mental Health Foundation reported that 42% of GPs have access to an exercise referral scheme, and of the GPs surveyed only 5% used exercise as one of their top three front-line treatments for depression, whilst 92% used anti-depressants as one of their three top treatments (MHF 2004). Less than half of the GPs surveyed felt exercise was an effective treatment for depression. Moreover, when exercise interventions are offered, they are often of little use to the client group. Women living with depression in the community regard the mainstream exercise regimes prescribed by their GP as a negative experience (Owen and Khalil, 2006). While the benefits of exercise to physical health are widely known, the benefits to mental health are still less well understood and accepted (MHF 2004). On the whole exercise appears to be a neglected intervention in mental health care. There is little or no mention of exercise as a treatment option in most standard mental health/illness texts or reports published by authoritative groups in mental health (Callaghan 2004). There are, however, notable

exceptions, The *National Quality Assurance Framework for Exercise* [NQAFE] (Department of Health [DH], 2001) acknowledges the strong causal evidence for the impact of exercise on mental health and offers detailed guidance to mental health workers interested in referring patients to exercise referral programmes.

There is a clear need for an intervention comprising physical activity that is accessible and appropriate to people with depression in particular for whom the evidence suggests exercise is a sound first-line treatment option; it is less expensive to deliver than many alternatives; promotes social inclusion; is popular; has few side effects; and the mechanism for delivery in a primary care context already exists in the form of exercise referral schemes (MHF 2004).

DESIGNING AN EXERCISE INTERVENTION FOR DEPRESSED PEOPLE

Several factors emerge from the literature and the research teams' previous work as vital to the design and delivery of such an intervention to depressed individuals. 'There is emerging evidence that people with serious mental illness canbe more physically active if interventions and lifestyle programmes are tailored to overcome the neurological, behavioural and social deficits associated with serious mental illness' (Robson and Gray 2007). 'Exercise therapy needs to be delivered in such a way that support for the patient is maximized. Embarking on behavior change is not easy, especially for a population with motivation difficulties, and it is more likely to be successful when that change is supported by well-trained specialist staff, able to devote their time and attention to helping people with their programme' (MHF 2004). In the scoping study that preceded this trial, Owen and Khalil (2006) found that women living with depression in the community expressed preferences for low-intensity exercise of particular activities in particular environments. Group projects were cited as preferable, with peers (of similar physical and mental health status); low impact activities such as swimming and walking were preferred. Rhythmic, aerobic forms of exercise, such as brisk walking, jogging, swimming, or dancing are most consistently effective in achieving mental health benefits (DoH 2004). All of these factors were taken into consideration when designing our programme to be emotionally supportive, friendly, sensitive and responsive to the specific needs of this group, and featuring low impact rhythmic exercise (brisk walking) within a facilitated group of peers, led by specialist staff.

RATIONALE

A tailored exercise programme, with exercise at a preferred exertion level and psychosocial support, has potentially greater benefit to women with depression than exercise-as-usual on prescription. Improving the physical health of people with mental illness is a national priority (Department of Health 1999, 2004, 2006). Physical health care for mentally disordered women, is an area that has been flagged up by the Department of Health in its national policy to address the disparities in providing services to mentally ill women (Department of Health 2003).

RESEARCH OBJECTIVES AND HYPOTHESES

1. To investigate the effect of a tailored programme of low effort physical activity and psychosocial support on global well-being; in a community-based sample of women living with depression; compared with a commonly prescribed programme of exercise-as-usual.

2. To capture relative attendance rates between the two groups.

3. To explore participants' experiences of the programme, as there is a paucity of qualitative studies of exercise as a treatment for depression (MHF 2004).

H_1 = A tailored exercise intervention will lead to better psychological, physiological and social wellbeing outcomes when compared with an intervention based on national recommendations.

H_2 = Women assigned the tailored programme will attend a greater number of sessions than women assigned the standard prescribed programme of exercise.

METHOD

The experimental exercise programme (experimental arm) was evaluated in a 'pragmatic randomised controlled trial' (PRCT), and compared with a programme of 'exercise-as-usual' (control arm) of the type commonly prescribed by General Practitioners. This design is especially suited to encompassing a complex intervention and informing everyday practice with evidence. In addition, the women in this study we defined very broadly as 'living with depression', as it is the presentation, and not a specific diagnosis, that leads to specific challenges for service providers. This was crucial as our aim was to target a programme to the women presenting to GPs as 'depressed' in functional terms with the aim of improving their daily situation. A mixed method approach was employed in data collection, analysis and interpretation, using both quantitative and qualitative methods and measures. It is rare to find studies investigating the role of exercise on health that use qualitative research methods (Callaghan 2004, MHF 2004), yet they allow researchers to intensively study the participants' experiences, and 'quantitative studies can fail to convey the richness of experience reported by those who employ exercise as a recovery strategy' (MHF 2004). Until now, 'there has been less focus on the social mechanism of interaction and support than is warranted' (DoH 2004). In this study, we sought to unpack the participants' experience of the programme, particularly the social aspects of participation. To this end quantitative measures were supplemented with a half-hour focus group at the close of each programme, and field notes were collected throughout every session of each programme. The motivational interviewing approach was employed in supporting the women in the experimental arm as it encourages ownership of behavioural change; belief in the possibility of change, an important motivator; and hope in a range of available possibilities. The Transtheoretical Stages of Change (TTM) model (Prochaska & DiClemente 1984) was utilised as a theoretical basis in behaviourally targeting the experimental programme.

The project had two arms – experimental and control. There were a total of seven programmes run, with approximately four women exercising together in each, at three different sites – local authority leisure centres - in Nottinghamshire. An independent researcher from the East Midlands Hub of the National Mental Health Research Network (MHRN) assigned the running order of control or experimental programmes to the locations, and randomly allocated the participants to each programme, using a computer generated randomizer from www.random.org. Participants in the control and experimental arm had an initial welcome session, during which they were welcomed to the study, formal face-to-face written consent was obtained, any housekeeping and other administration were completed, and baseline measures were administered. Measures took around half an hour to administer, short forms were used wherever possible. Administration was carried out by appropriately qualified personnel from the MHRN, independent to the project, to minimise any researcher bias.

The experimental group received 12 sessions of intervention, at a rate of three sessions per week for four weeks. Each session comprised; fifteen to twenty minutes of motivational support, run by a qualified rehabilitation psychologist and overseen by a qualified health psychologist; a half hour preferred exertion level exercise session run by a qualified sports physiotherapist. Participants preferred intensity (chosen exertion level) was established using the Borg RPE scale (Borg,1998); heart rate measures were taken using heart monitors.

The control group received 12 sessions of intervention, at a rate of three sessions a week for four weeks. Each session comprised fifteen to twenty minutes of healthy lifestyles education, and a half hour 'exercise –as-usual' session, designed in accordance with national guidelines and run by a qualified sports physiotherapist.

The experimental and control interventions were manualised, and a protocol devised for both the motivational interviewing and healthy lifestyles components (refer to appendices H, J and K). This ensured transparency of approach, replicability and minimised researcher effects in delivery.

FINDINGS

The research hypotheses were supported. Women on the experimental arm experienced a statistically significant improvement in their mood, physical health, sense of wellbeing, self-esteem and quality of life. They attended significantly more sessions than women assigned 'exercise-as-usual'. They felt they had achieved these gains via a positive, comfortable experience which encouraged regular continued attendance. '*I feel more confident in my physical self and my emotional self. I do think it's helped with my mood.*' Whereas women receiving 'exercise as usual' did not experience any statistically significant benefits, were less likely to continue attending, and were markedly less enthusiastic.

CONCLUSIONS

- The intervention group demonstrated significant benefit across a range of psychological, social and physical outcomes constituting 'health'. The control group did not report such benefits.
- The intervention group achieved these gains via a positive, comfortable experience.
- The positive nature of the experience encouraged regular attendance.
- Delivering an intervention informed by service users and responsive to them increased uptake and benefit to users.

RECOMMENDATIONS

Several areas key to improving the wellbeing of women living with Depression through exercise participation coupled with psychosocial support have been identified in this study. Recommendations are made regarding these areas, encompassing general principles for delivery and design of exercise interventions and for further research.

PROVISION OF EXERCISE INTERVENTIONS FOR PEOPLE WITH MENTAL ILLNESS

- Mental health service providers should include exercise promotion in each care package for women diagnosed with Depression.
- All GPs should offer women presenting with mild or moderate depression the opportunity for referral to exercise programmes tailored to their needs.
- It needs to be clear to the target group that the exercise offered is specifically tailored to their needs.
- Prescribed exercise programmes need to focus on improving, and measuring improvement in, health and social care outcomes.
- Provide primary care practitioners, MHNs and local authority leisure centre staff with basic training and manualised guidelines for recruiting and supporting depressed women in exercise activity, continued attendance without dropping out, and return to exercise after periods of crisis.

DESIGN OF EXERCISE PROGRAMMES

- Exercise programmes should include service user involvement in design and delivery, and systematically collect and respond to feedback from users.

- Exercise programmes designed for women living with Depression need to be structured to facilitate attendance in the early stages of establishing an exercise routine.

- Exercise programmes must pay attention to the value of exercise as a normalizing experience that promotes social inclusion, focusing on group exercise in a supportive friendly environment.

- Exercise programmes should be evaluated against a range of wellbeing outcomes with special reference to continued attendance as a discrete measure of perceived benefit.

RESEARCH ON EXERCISE AND MENTAL HEALTH

- Further qualitative research exploring what makes for an acceptable, accessible exercise programme is needed. A longitudinal study evaluating the longevity of lifestyle change and benefit, as well as issues around returning to exercise following a crisis is recommended.

- Further research focusing on how the social mechanisms of support, interaction and affiliation are linked to exercise adherence is needed.

- There is a need also for more focus on HOW the social mechanisms of support, interaction and affiliation might work within exercise programmes.

FURTHER PLANNED RESEARCH IN THIS PROGRAMME

A pragmatic randomised controlled trial of a preferred intensity exercise programme to improve physiological and associated psychological, social and wellbeing outcomes of young people living with depression is the next planned study in this sequence.

In addition, a multi-site trial of the tailored exercise programme for women with depression is planned, utilizing the work described here as a pilot study.

INTRODUCTION

BACKGROUND

THE LINK BETWEEN PHYSICAL AND MENTAL ILLNESS

Health is 'a state of complete physical, mental, and social well-being and not merely the absence of disease, or infirmity' (WHO). Within the notion of global wellbeing, there are physical, psychological and social constructs, and between them is a complex interplay. For example, a growing body of research demonstrates the impact of mental health on physical health, and vice versa, and how the social environment can act physiologically to cause physical illness (Mentality 2003, MHF 2006, DoH 2006). Conversely, people exhibiting emotional wellbeing appear to benefit from a protective effect (Goodwin 2000).

People with mental health problems are more likely to experience physical ill health than the rest of the population, they have high levels of physical morbidity and mortality (Phelan, Stradins et al. 2001; Nocon 2004, NIMHE/Mentality 2004). This is an enduring theme in the literature base and although government policy and initiatives, and initiatives from national independent organizations seek to improve the situation, as yet little or no improvement is evident in the literature, or to the service users (Bradshaw 2005, Owen & Khalil 2006). For both morbidity and mortality the causes and outcomes are complex, and a range of variables contribute (Robson and Gray 2007), some originating from the patient, such as social deprivation and lifestyle choices; some originating within the care sector, such as side effects of psychiatric medication, needs being unmet, and insufficient practitioner training in meeting physical health needs for this group. Research has shown that mental disorders are associated with an increased prevalence of physical disorders (Knutsen and Du Rand 1991), and certain psychiatric and physical disorders are also known to be associated with each other, for example in elderly people (Lindesay 1990). People with serious mental illness have higher rates of cardiovascular disease (Brown et al 2000), respiratory disease (Brown 1997, Sokal et al 2004), cancers (Schoos and Cohen 2003), diabetes (Holt and Peveler 2005) and HIV (Blank et al 2002). Psychiatric medication can increase the risk of other illnesses such as diabetes (Newcomer et al 2002) and poor dental health as a result of reduced saliva (Friedlander and Mardler 2002, McCreadie 2003). All anti-depressants and some anti-psychotics are associated with sexual dysfunction and disturbances in menstrual cycle (Hummer & Huber 2004Halbriech & Kahn 2003). Antipsychotics in particular are commonly attended by physical side effects such as weight gain, and may cause insulin sensitivity leading to food cravings (Werneke et al 2003). In addition, people with diagnosed mental disorders may well attach lower priority to physical health than is the norm (Liebermann and Coburn 1986). People with mental illness have been demonstrated to be more likely to have an unhealthy lifestyle, and to 'self-medicate' with recreational drugs and alcohol, and also with cigarettes and with food (Jeste 1996, Harris and Barraclough 1998, Brown 1999, Phelan et al 2001, Ryan and Thakore 2002, Lambert 2003, Meiklejohn 2003). Graham (2004) points out that like environmental risks, at the lower end of the socioeconomic spectrum where mental health service users are most likely to be, behavioural risks to health are more prevalent. Smoking in particular has been demonstrated to contribute to higher mortality, but risky sexual practices, poor nutrition and sedentary lifestyles also pose a health threat (Brown 1999, Lambert et al 2003). Smoking causes an increase in dopamine that has been demonstrated to alleviate some psychiatric symptoms and as such can be seen as self-medication in its truest sense (Goff et al 1992, Dalack et al 1999); smoking is embedded in psychiatric care to the extent that it is frequently promoted as a means of behaviour management (McNeill 2001). A mentally ill person's weekly intake of fruit and vegetables is less than half the recommended level (McCreadie 2003). Many people with mental illness do not take enough exercise (Brown 1999, Ward and Mason 2000, McCreadie 2003); the sedating effects of some medications can make it more difficult to get active (Robson and Gray 2007). Mentally ill women are at particular risk of obesity (Phelan, Stradins et al. 2001), obesity in turn raises the likelihood of developing diabetes, hypertension, respiratory difficulties and heart disease (WHO 2003).

Depression in particular has an impact on a range of physical health outcomes; it is associated with asthma, arthritis and diabetes (Turner 2000), is a risk factor for stroke (Jonas 2000, Ostir 2001) and increases the risk of heart disease by four times (Hippisley-Cox 1998).

WHY IS THE PHYSICAL HEALTH OF THE MENTALLY ILL SO POOR?

Addressing the poor physical health of mental health service users has been identified as a national priority (Department of Health 1999), however service users report that once they have a psychiatric diagnosis their physical health needs are disregarded (Sayce 2000). The evidence supports this claim (Brugha 1989, Gournay 1996, Phelan 2001), though the reasons for the lower standards of care may not be explained by stigma alone. Monitoring of physical health of the mentally ill is poor (Burns & Cohen 1998, Paton et al 2004, Greening 2005), despite a number of guidelines to inform practice (NICE 2002, Marder et al 2004), and provision of health education/promotion by community practitioners is 'generally unsatisfactory' (Gournay 1996). Mental health practitioners may be unsure about who should be responsible for physical health care (Dean 2001, Nash 2005), and perceive their main role as facilitating mental health and can be influenced by this (Meddings 2002, Bradshaw 2005), and a perception of mental health service users as being disinterested in their own physical health (Dean 2001, Friedli 2002). There is some indication in the literature that people with mental illness may be less likely to report physical symptoms unless asked about this, perhaps due to reduced pain sensitivity, commonly associated with schizophrenia and also with some antipsychotic medication (Dworkin 1994, Jeste 1996). Mental health care reform has led to the development of community based services, but physical health care is not necessarily a priority (Phelan 2001). As greater numbers of adults with serious and enduring mental illness have moved into community accommodation, responsibility for meeting their physical health needs is often unclear (Kendrick 1992; Beecroft, Becker et al. 2001). Another contributing factor to unmet physical health care need is the way in which our health services are organised, with somatic and mental disorders diagnosed and treated separately from each other. This has led to practitioners skilled at treating one but not the other (Knutsen and Du Rand 1991, Gray 1999, Nash 2005), despite their intrinsic inseparability, underlined by the WHO definition of good health. Lack of training received by health professionals contributes to the poor physical health of people with mental illness (Gray and Robson 2006).

Whilst a growing body of research has focused on the physical health problems of adults with mental illness; less is known about acceptable and appropriate practice regarding the provision of lifestyle interventions to this client group (Bradshaw 2005).

THE HEALTH BENEFITS OF PHYSICAL ACTIVITY

There is consistent evidence that physical activity is beneficial across a range of physiological, psychological, and social outcomes that comprise global well-being as defined by WHO (Mental Health Foundation 2004, DoH 2004). In addition, regular exercise improves musculoskeletal health and is associated with reduced risk of premature death and of many life-threatening illnesses such as coronary heart disease, stroke, diabetes and cancer (Thompson 1994, DoH 2004). Exercise can also help people to function better through alleviation of stress and improved sleep (Kubitz et al 1996, Youngstedt et al 1997, Sherill et al 1998), improve mood (Biddle 2000) and self-perception (Sonstroem 1996, Spence 1997, Fox 2000), all of which can alleviate negative affect in a person experiencing a mood disorder (Van de Vliet 2002). A good exercise habit can reduce the risk of suffering clinical depression (Paffenberger et al 1994, Dunn 2001, DoH 2004). Ideally people need to exercise with sufficient intensity for 20-30 minutes three to five times a week to experience health benefits, though this can be split into ten minute segments (Ekkekakis et al 2000, British Heart Foundation 2003, Callaghan 2004, DoH 2004). Sedentary individuals may need to be physically active for 45-60 minutes each day to maintain a healthy weight (DoH 2004). Benefits are observed regardless of age or socioeconomic status (DoH 2004).

THE BENEFITS OF PHYSICAL ACTIVITY TO THE MENTALLY ILL

Encouraging regular exercise represents an opportunity to tackle many of the inter-related health problems facing individuals with a mental disorder, such as low self-esteem, obesity, elevated blood pressure, with knock-on effects on other problems, for example lowering the risk of stroke (DoH 2004). In addition to improving general health and wellbeing, exercise has been shown to have beneficial effects on specific mental illness outcomes, for example running has been advocated as a more effective antidote to depression than psychoanalysis (Greist et al 1979). A recent World Health Organisation Report (WHO, 2000) shows that depression is a significant mental health problem afflicting people living in all member states. Among males it is ranked 8th accounting for 2.8% of Disability Adjusted Life Years (DALY's). Among females it is ranked 3rd accounting for 5.8% of DALY's. Empirical and anecdotal evidence show that exercise may have an anti-depressant effect in healthy individuals (North et al., 1990; DiLorenzo et al., 1999), and among those with profound multiple disabilities (Green & Reid, 1999). Physical exercise has been shown to be effective as a treatment of mild, moderate and severe clinical depression, and can be as effective as psychotherapy or medication in the long term (Byrne & Byrne 1993, Scully et al 1998, Craft 1998, Blumenthal 1999, Biddle 2000, Mutrie 2000, Lawlor & Hopker 2001, DoH 2004, MHF 2004). In 2000, Biddle et al concluded that 'overall, the evidence is strong enough for us to conclude that there is support for a causal link between physical activity and reduced clinically defined depression', Daley agreed in 2002, as did Craft and Perna in 2004, that there is strong evidence for the positive effect of exercise on mental health. In the face of the growing body of evidence, The chief medical officer's 2004 report also concurred that 'physical activity is effective in the treatment of clinical depression' and the 2004 white paper 'Choosing health' concluded that regular physical activity reduces the risk of depression and has positive mental health benefits such as enhanced mood and self-esteem. Exercise offers an alternative to medication such as SSRIs (selective serotonin reuptake inhibitors) for treatment of depression (Scott 1996); SSRIs can be extremely effective, but are associated with unpleasant and worrying withdrawal and side effects, such as increased risk of self-harm and suicide (MHF 2004). When used as an adjunct to medication, exercise improves chances of recovery (Babyak et al 2000). In 1987 the US National Institute Mental Health produced a consensus statement on the mental health effects of exercise. The expert panel concluded that exercise is (i) positively linked with mental health and wellbeing, (ii) reduces stress and state anxiety, and (iii) has emotional benefits for all ages and both genders (Morgan & O'Connor 1988). North et al. (1990) reviewed the results of narrative and meta-analytic reviews investigating the effect of exercise on depression. In this review exercise is suggested to improve depression by changing people's daily routine, increasing their interactions with others, helping them lose weight, participate in outdoor recreation and master difficult physical and psychological challenges. Evidence that biological factors may explain the beneficial effects of exercise on depression derives from research showing that exercise promotes the secretion of neurotransmitters like serotonin (Ransford, 1982; Morgan, 1985). Also, evidence from animal studies suggests exercise stimulates the secretion of endogenous morphines ('Endorphins') and produces a state of euphoria (Pert & Bowie, 1979). Exercise may also operate on mood through social mechanisms, by enabling new social networks and relationships, by boosting self–esteem via attainment of new skills and improved physical fitness and body image, and by creating a diversion from negative thoughts (Csikzentmihali 1990, Daley 2002, MHF 2004). On the basis of a systematic review of the effect of exercise on depression as measured by the Beck Depression Inventory (BDI) scores, Lawlor and Hopker (2001) reported that exercise produced a large decrease in depression symptoms (effect size = 1.1) when compared with no treatment. However, most of the studies in this review had methodological weaknesses which may have exaggerated results in favour of the intervention, adjusting for this a medium effect size is still apparent (Callaghan 2004), and as Mutrie (2002) points out, Lawlor and Hopker offer compelling evidence for the benefits of exercise in depression and unlike drug therapy, exercise has few negative side effects. Schizophrenia is one of the most disabling of all mental illnesses. Exercise is shown to reduce auditory hallucinations, raise self-esteem, and improve sleep patterns and general behaviour in people living with schizophrenia (Faulkner and Biddle 1999, Faulkner & Sparkes, 1999). Physical activity has some beneficial effects for people with anxiety disorders too, along with phobias, panic attacks and stress (Hassmen 2000, O'Connor et al 2000, Taylor 2000, Iwasaki 2001). Petruzzello et al. (1991) conducted 3 meta-analyses to examine the effect of acute and chronic exercise on state (current) anxiety, trait (dispositional) anxiety and psychophysiological correlates of anxiety derived from published and unpublished studies (n=104) reported between 1960 and 1989. The results from these

detailed meta-analyses show that aerobic exercise is associated with reductions in anxiety, though exercise of more than 20 minutes duration appears necessary for reduction in anxiety levels. There are several views that seek to explain the beneficial effects of exercise on anxiety. One view suggests that exercise raises body temperature and reduces muscle tension similar to the effect of having a warm bath – the so-called thermogenic hypothesis (Raglin & Morgan, 1985). Another view suggests that exercise stimulates activity in the sympathetic nervous system (SNS); adrenaline levels are increased and this has an arousing effect. When the SNS is activated it provides a catalyst for parasympathetic nervous system (PNS) activity; acetylcholine is released and this has a calming effect. This is known as the Opponents Process Model (Solomon, 1980). Exercise is also thought to distract people from stressful events thereby reducing the anxiety provoking impact of these events (Bahkre & Morgan, 1978).

To conclude, it seems that the process of being physically active, rather than fitness itself, is primarily responsible for benefits to mental wellbeing, through a complex mix of biochemical, physiological and psychosocial mechanisms (DoH 2004). These benefits are now recognized in official national guidance on health care, and in particular for depressed individuals, for example, NICE (the National Institute for Clinical Excellence 2004) recommend that sufferers of mild depression of all ages are advised of the benefits of participating in an exercise programme of a moderate level three times a week for 10-12 weeks. Mental health organizations also now recommend exercise as a treatment option for mild to moderate depression, in 'Up and Running' (2004) the Mental Health Foundation review the evidence and present a strong case for exercise referral as 'inexpensive, effective, and having coincidental benefits'.

EXERCISE INTERVENTIONS FOR THE MENTALLY ILL

Ddespite the fact that consultation rates are three to four times higher than for the general population (Seymour 2003), people with mental illness are less likely to be offered health promotion interventions, or exercise prescriptions (Brown 1999, Burns and Cohen 1998, Cohen and Hove 2001, Friedli and Dardis 2002). Participants in one scoping study felt that their physical health isn't taken seriously as a direct result of their mental health status (Owen & Khalil 2006). Evidence shows that health promotion measures need to be carefully targeted to this group, campaigns to encourage childhood immunization and cancer screening have widened the inequalities in uptake. 'A major challenge for the health and social care sector is to reduce barriers to accessing services which prevent illness and save lives' (Graham 2004). 'Health promotion information rarely makes clear its importance and relevance to people with severe mental illness' (Mentality 2003), availability of appropriate, targeted resources is scant (Sherr 1998), and service users have noted this lack, and feel that health promotion campaigns are 'not for us' (Freidli 2002). GPs' clinical guidelines advise that anti-depressants should not be used as a first-line treatment for mild depression, yet in the absence of other interventions, 78% have prescribed anti-depressant medication despite believing that an alternative approach might have been more appropriate (MHF 2004). In 2004, the Mental Health Foundation reported that 42% of GPs have access to an exercise referral scheme, and of the GPs surveyed only 5% used exercise as one of their top three front-line treatments for depression, whilst 92% used anti-depressants as one of their three top treatments (MHF 2004). Less than half of the GPs surveyed felt exercise was an effective treatment for depression. Moreover, when exercise interventions are offered, they are often of little use to the client group. Women living with depression in the community regard the mainstream exercise regimes prescribed by their GP as a negative experience (Owen and Khalil, 2006). While the benefits of exercise to physical health are widely known, the benefits to mental health are still less well understood and accepted (MHF 2004). On the whole exercise appears to be a neglected intervention in mental health care. There is little or no mention of exercise as a treatment option in most standard mental health/illness texts or reports published by authoritative groups in mental health (Callaghan 2004). There are, however, notable exceptions, and increasingly, some mental health professionals are advocating exercise as a therapeutic tool in the treatment of various mental health problems. A keen advocate of using exercise in mental health care is psychologist Kate Hays who has used exercise in her work with clients in a career spanning more than 25 years. In *Working it Out: Using Exercise in Psychotherapy* Hays (1999) recommends that practitioners prescribe exercise to aid the recovery of people with mental health problems. She also provides detailed evidence-based information on the effects of exercise on mental health and well being, the use of different exercise regimens tailored to client needs and abilities, as well as addressing ethical issues relevant to exercise. In a review article that examined the effects of exercise on mental health

Chung and Baird (1999) also recommend the use of exercise as a therapeutic tool. D'Silva (2002) offers a concise summary of the ways in which various forms of exercise can improve mental health and well being and recommends for example boxing or tennis for dealing with anger or frustration or team sports for loneliness or poor social skills. The *National Quality Assurance Framework for Exercise* [NQAFE] (Department of Health [DH], 2001) acknowledges the strong causal evidence for the impact of exercise on mental health and offers detailed guidance to mental health workers interested in referring patients to exercise referral programmes.

There is a clear need for an intervention comprising physical activity that is accessible and appropriate to people with depression in particular for whom the evidence suggests exercise is a sound first-line treatment option; it is less expensive to deliver than many alternatives; promotes social inclusion; is popular; has few side effects; and the mechanism for delivery in a primary care context already exists in the form of exercise referral schemes (MHF 2004). Provision of quality services that are responsive to the needs of users is a core rationale of Modernising Mental Health Services, the NSF for mental health, the NHS Plan, and Modernising Health and Social Services (Department of Health 1998, 1999, 2000, 2000a). Standard one of the NSF for mental health requires health and social services to combat the discrimination experienced by those with mental health problems and to promote their social inclusion (Department of Health 1999). 'Assessing, identifying and responding to the physical health needs of mental health service users is integral to the realisation of standard one,…for this vulnerable group of people' (Mentality 2003). The NSF states explicitly that services must '…have the skills and necessary organisational arrangements to provide the physical health care and other primary care support needed…' to people with mental illness.

DESIGNING AN EXERCISE INTERVENTION FOR DEPRESSED PEOPLE

Several factors emerge from the literature and the research teams' previous work as vital to the design and delivery of such an intervention to depressed individuals. 'There is emerging evidence that people with serious mental illness can… be more physically active if interventions and lifestyle programmes are tailored to overcome the neurological, behavioural and social deficits associated with serious mental illness' (Robson and Gray 2007). Harnessing motivation and providing effective support in a behavioural intervention can be beneficial to service users (Schneidermann 2006), motivational and self-esteem issues were cited as influential in health behaviour by participants in the scoping study (Owen & Khalil 2006). Low self-esteem was another common experience, and obstacle to exercise initiation, and the perception of exercise as 'not for me'. Goal attainment can be influenced by careful behavioural targeting of an intervention (Gollwitzer, 1999). 'Exercise therapy needs to be delivered in such a way that support for the patient is maximized. Embarking on behavior change is not easy, especially for a population with motivation difficulties, and it is more likely to be successful when that change is supported by well-trained specialist staff, able to devote their time and attention to helping people with their programme' (MHF 2004). Exercise at a preferred exertion level is more beneficial for depressed people (McDevitt et al, 2005). In the scoping study that preceded this trial, Owen and Khalil (2006) found that women living with depression in the community expressed very definite preferences for low-intensity exercise of particular activities in particular environments. Group projects were cited as preferable, with peers (of similar physical and mental health status); low impact activities such as swimming and walking were preferred. Rhythmic, aerobic forms of exercise, such as brisk walking, jogging, swimming, or dancing are most consistently effective in achieving mental health benefits (DoH 2004). An exercise 'buddy' was especially valued. Adherence to specifically tailored programmes can be similar to other forms of treatment, if the programme is pitched appropriately adherence in depressed people can be comparable to the general population (Martinsen 1993). It is rare to find studies investigating the role of exercise on health that use qualitative research methods (Callaghan 2004, MHF 2004), yet they allow researchers to intensively study the participants' experiences, and 'quantitative studies can fail to convey the richness of experience reported by those who employ exercise as a recovery strategy' (MHF 2004).

All of these factors were taken into consideration when designing our programme to be emotionally supportive, friendly, sensitive and responsive to the specific needs of this group, and featuring low impact rhythmic exercise (brisk walking) within a facilitated group of peers, led by specialist staff. Qualitative measures were included in the study design in order to help the research team to unpack the participants' experience of the programme.

RATIONALE

A tailored exercise programme, with exercise at a preferred exertion level and psychosocial support, has potentially greater benefit to women living with depression than exercise-as-usual on prescription. Improving the physical health of people with mental illness is a national priority (Department of Health 1999, 2004, 2006). Physical health care for women living with Depression, is an area that has been flagged up by the Department of Health in its national policy to address the disparities in providing services to mentally ill women (Department of Health 2003).

RESEARCH OBJECTIVES AND HYPOTHESES

1. To investigate the effect of a tailored programme of low effort physical activity and psychosocial support on global well-being; in a community-based sample of women living with depression; compared with a commonly prescribed programme of exercise-as-usual.

2. To capture relative attendance rates between the two groups.

To explore the participants' experiences of the programmeH_1 = A tailored exercise intervention will lead to better psychological, physiological and social wellbeing outcomes when compared with an intervention based on national recommendations.

H_2 = Women assigned the tailored programme will attend a greater number of sessions than women assigned the standard prescribed programme of exercise.

METHOD

DESIGN

PRAGMATIC RANDOMIZED CONTROLLED TRIAL

The exercise programme was evaluated in a 'pragmatic randomised controlled trial'. This design is especially suited to encompassing a complex intervention such as our programme and informing everyday practice with evidence. In addition, the women we aimed to improve outcomes for we have defined very broadly as 'living with depression', as it is the presentation, and not specific diagnoses, that leads to specific challenges for service providers. The pragmatic randomised controlled trial is particularly suited to reflecting the heterogeneity of patients encountered in clinical practice and keeping exclusion criteria to a minimum (Hotopf, 2002). This was crucial as our aim was to target a programme to the women presenting to GPs as 'depressed' in functional terms with the aim of improving their daily situation.

A mixed method approach was employed in data collection, analysis and interpretation, using both quantitative and qualitative methods and measures. In order to meet our stated research objectives a positivistic approach was essential. However, there have been calls from researchers and mental health bodies working in this area for more qualitative data collection and analysis to unpack the nature of why exercise seems a preferred treatment choice, and what makes a helpful exercise programme, and to 'convey the richness of experience reported by those who employ exercise as a recovery strategy' (MHF 2004). For this reason a substantive qualitative strand was included in the study design. Moreover, the nature of a pragmatic controlled trial means that it is appropriate for a real world intervention such as this, yet while such a design will reveal whether the intervention is helpful, it will not necessarily be clear how the intervention achieves this, as variables are not subject to such stringent control as in a traditional RCT. Again, qualitative data collection in the form of focus groups at the end of each programme, but also in the form of ongoing

field notes throughout each programme are essential in documenting and exploring the reasons why exercise may be helpful.

USER INVOLVEMENT IN THE RESEARCH

'Making Waves' (a local user group), http://www.makingwaves.org/ collaborated with the team from the outset in an advisory capacity. It has assisted with recruitment of participants by promoting the study among their members and contacts in the voluntary sector. In addition, two service users sat on the steering panel, providing regular input into the monitoring and ongoing evaluation of the study from a user perspective. One service user was experienced at this, one was in training. The research team facilitated the training process.

RANDOMISATION

Randomisation was conducted by a researcher from the Mental Health Research Network, unconnected with the study. Once a study site had been identified, a computer 'coin flip' was conducted to decide the running order of programmes, experimental or control.. Randomisation of participants was carried out prior to inclusion on the basis of a computer generated random sequence list from www.Random.org. A random sequence list comprising all available places on an experimental or control exercise programme at each project site was generated. Participants were assigned to these spaces in order of consenting to take part in the study. To prevent too great an imbalance in the number of participants in each of the two trial arms at each of the venues, randomisation was carried out in blocks of randomly varying sizes, with block size hidden from the individual responsible for informing the participant of their allocation. This limited the project team's ability to predict the allocation of participants recruited to the study towards the end of blocks.

SAMPLING AND RECRUITMENT

SAMPLE

Recruiting participants from a group characterized by low motivation and sedentary lifestyles, who do not see such initiatives as 'for them', presented a challenge. In addition, exercise studies tend to experience difficulty recruiting. A wide-ranging approach was employed, using all possible avenues, (see appendix A and figure one for a flow chart of the promotion and recruitment procedure) To detect a medium effect size (P=0.54) of differences in outcomes between the experimental and control group, with 80% power at a 5% significance level, allowing for estimated attrition of 10% with a pragmatic RCT design, a sample size of N=140 is required (Cohen 1992).

PROMOTION PROCEDURE

The project team set up a project website, carefully piloted and targeted at the sample group, with an automated system for acquiring more information about the project. A dedicated telephone line with a named member of the project team, a female, was also provided. A poster/flyer was designed to circulate widely, again carefully targeted to appeal to the intended audience (see Appendix A).

The project team sent information letters to primary (GP surgeries in both PCTs) and secondary services (Nottinghamshire Healthcare NHS Trust Mental Health Services), detailing the study and inviting clinicians to assist us in identifying potential participants. An assent form was included for each service/clinician to return if potential participants agreed to do this. Those services agreeing to engage with us received a pack containing a poster to display where potential participants could see it, a set of flyers to hand to potential participants, and a flow chart to guide each clinician through the inclusion criteria (see appendix C). Posters presented very clear information about eligibility criteria, to avoid any potential disappointment to interested parties. Clinicians were requested to

hand the flyer out to every consecutive potential participant (to maximise opportunity for interested women to participate and minimise selection bias), having worked through the inclusion criteria. In the event of the potential participant wanting to ask further questions at this stage, the clinician was instructed to refer them to the project telephone hotline number provided on the flyer, where they could contact a named member of the project team. This minimised clinicians' time commitment, and also any misperception that they were connected with the trial in any other way than drawing attention to it, or that it may constitute a treatment. The clinicians' flow chart also included a reminder to the potential participant that this was a research study and not a course of prescribed treatment.

In addition our collaborating service user group 'Making Waves' and the East Midlands hub of the Mental Health Research Network publicised the programme among its members and relevant independent and voluntary sector organisations and contacts, using the project promotional poster and information flyer. MHRN staff also made visits to interested organizations using a lay-language information sheet of their own design (see appendix D). Furthermore, we promoted our study in the local media (see appendix E: press release), and on the University of Nottingham web pages.

INCLUSION CRITERIA

Please see Appendix C. Potential participants were:

- living with depression*
- aged 45-65 (age at first session of programme)**
- female**
- living in the community
- resident within Nottinghamshire (personal address has Nottinghamshire postcode)

*'Living with depression' was defined as currently being monitored by, or receiving treatment for depression from, any primary or secondary services. **We restricted the study to women aged 45-65 because they constitute a group identified as particularly in need of such an intervention in our previous research (Owen & Khalil 2006).

Exclusion criteria:

- Women who, at the time of the study, are unable to participate on account of any injury or physical health problem that precludes their participation.
- Women participating in research that may undermine the scientific basis of the study.

This selection procedure also assumed reading ability in English language on behalf of the participant, at a level commensurate with the national average. Our study did not exclude women on any other diversity constructs such as race, religion, sexual preference, level of education or disability.

CENTRAL ALLOCATION SYSTEM

Potential participants picked up an information flyer from a user group, or saw the posters, or had a flyer handed to them by their clinician. The flyer/poster instructed them to visit the project website and/or to call a project telephone number if they were interested in participating. The researcher answering the phone screened the potential participant using the inclusion/exclusion criteria. . Participants were invited to ask questions at this stage. Provided the potential participant indicated a continued desire to participate, their contact details were taken by the researcher, and a further information pack was sent out, describing the exercise programme in full with an acceptance slip to be completed and returned in a prepaid envelope. An important part of the pack was a reminder to participants to check with their GP prior to commencing the exercise programme if they had doubts about their fitness to participate. A standard letter to the participant's GP was included in the pack for them to hand to their GP. Provided they were

eligible, upon receipt of the acceptance slip, the researcher forwarded the assigned participant code to an independent operative at the MHRN (see RANDOMISATION below). The MHRN staff filled in the participant code on the next available programme slot which could be experimental or control. Participants were allocated to the gym appropriate to their home address (to minimise inconvenience in travelling). Upon attendance at the introductory session of the programme, participants were talked through the information sheet and issues around random allocation. They were invited to ask questions, reminded of their right to withdraw at any stage, and formal written consent was obtained. This two-stage consent procedure with consent-in-principle, followed by formal face-to-face written consent, was demanded by the methodology of the intervention, in order that the team could manage the logistics of random allocation along with convening the exercise programmes in a spread of geographical locations. Reminder telephone calls were made to participants one week before their programme was due to commence, letters were sent in the absence of a telephone, timed to arrive one week before. Participants were once again encouraged to raise any questions. Participants were reminded again to check with their GP prior to commencing the programme.

OUTCOME MEASURES

A battery of outcome measures was devised and piloted by the project team, advised by the steering group, to capture change across a representative selection of the spectrum of physical, psychological and social components of wellbeing.

PRIMARY OUTCOME MEASURE

The primary outcome measure was responses to the BDI-II (Beck Depression Inventory version 2 (Beck A T 1996)) at the plenary session of the programmes. The most widely used instrument for detecting the likelihood of depression, the BDI–II consists of 21 items to assess the likelihood and intensity of depression in clinical and non-clinical samples. Each item is a list of four statements arranged in increasing severity about a particular symptom of depression, scored on a scale from f 0 to 3. The cut-offs are 0-13 - minimal depression; 14-19 - mild depression; 20-28 -moderate depression; and 29-63 - severe depression. Higher total scores indicate more severe depressive symptoms. The new items bring the BDI–II into alignment with DSM–IV criteria.

SECONDARY OUTCOME MEASURES

Secondary outcome measures were chosen to capture change across a representative selection of physical, psychological and social components of wellbeing.

Physiological measures*

Participant's estimated weekly exercise activity – duration (minutes per week), type of activity, self-rated level of exertion (light/moderate/strenuous). This was reported on a questionnaire schedule designed for this trial, modelled upon a similar scale utilized in previous exercise research by the team (Callaghan et al 2010).

Resting heart rate (Centers for Disease Control and Prevention, 2006): A universally recognized measure of physical fitness.

Perceived effort: The Rating of Perceived Exertion scale (Borg 1998). A method of determining physical activity intensity is the Borg Rating of Perceived Exertion scale (RPE). Perceived exertion is how hard you feel your body is working. It is based on the physical sensations a person experiences during physical activity, including increased heart rate, increased respiration or breathing rate, increased sweating, and muscle fatigue. 'Although this is a subjective measure, a person's exertion rating may provide a fairly good estimate of the actual heart rate during physical activity' (Borg, 1998). The scale ranges from 6 to 20, where 6 means "no exertion at all" and 20 means "maximal exertion." Practitioners generally agree that perceived exertion ratings between 12 to 14 on the Borg Scale suggests that physical activity is being performed at a moderate level of intensity.

*Physiological measures were collected throughout the programme.

Psychological measures

Mental wellbeing: GHQ12, 12 item General Health Questionnaire (Goldberg, 1992). The General Health Questionnaire (GHQ) screens for non-psychotic psychiatric disorders. The 12 item version is recommended for research purposes. This study used Goldberg's original scoring bimodial method. In this method response categories score 0, 0, 1, and 1 respectively. This gives scores ranging from 0 to 12. A score of 4 or more is considered indicative of 'caseness' - mental health problems.

Physical health status: SF12, The SF-12vII Health Survey (Ware, 2002). The SF-12 is a self-reporting multipurpose scale used for assessing health-related quality of life for eight concepts of physical and mental health: physical functioning, role limitations due to physical health problems, role limitations due to emotional health problems, social functioning, emotional well-being, pain, energy and/or fatigue, and general health perceptions. SF-12 is a standardized measure of health status. Items are scored on Likert scales, a high score indicates poor health.

Self esteem: RSES, The Rosenberg Self-Esteem Scale (Rosenberg, 1989). The Rosenberg Self-Esteem Scale is a standardized scale and was used to assess global self-esteem and self-acceptance. This is a ten item self-rating Likert scale with items answered on a four point scale, from strongly agree to strongly disagree. The higher the score, the higher the self esteem, 14-25 is considered normal, below 14 indicates low self-esteem.

Social measures

Quality of life: The QLDS, Quality of Life in Depression Scale (Hunt & McKenna,1992). The QLDS is a standard measure of needs-based quality of life of patients with depression. The theoretical basis for the instrument is that life gains its quality from the ability and capacity of the individual to satisfy his or her needs. The scale covers emotional reactions, social isolation, energy level, sleep, physical mobility, and pain. The QLDS, consisting of 34 items related to depression, scored binomially (0,1) has demonstrated reliability and validity. On this scale, numerically higher scores depict lower QOL.

Social support: The Multidimensional Scale of Perceived Social Support (Zimet,et al , Dahlem N W et al. 1988). A 12-item questionnaire that assesses participants' perception of the role that friends, family and peers play in their lives. Respondents rate items on a seven-point Likert scale with higher scores corresponding to greater social support. Only the total social support score was used in this study. Previous research has provided psychometric support for the validity and reliability of this measure in adult populations (Dahlem et al 1991, Zimet, 1990).

QUALITATIVE ELEMENT

It is rare to find studies investigating the role of exercise on health that use qualitative research methods (Callaghan, 2004), yet they allow researchers to study intensively the participants' experiences.. In this study, quantitative measures were supplemented with a substantive qualitative exploration of the participant's experiences. A long focus grouplasting approximately XXX was conducted at the close of each programme; moreover field notes were collected throughout every session of each programme, to document and explore the journey that the women made. Participants often added input to these field notes, mentioning aspects of their journey that they felt were important to the experience. The focus group topic guide was informed by the literature base and the service user views from the preceding scoping study (Owen & Khalil 2006), and advised by the project steering group (see Appendix F).

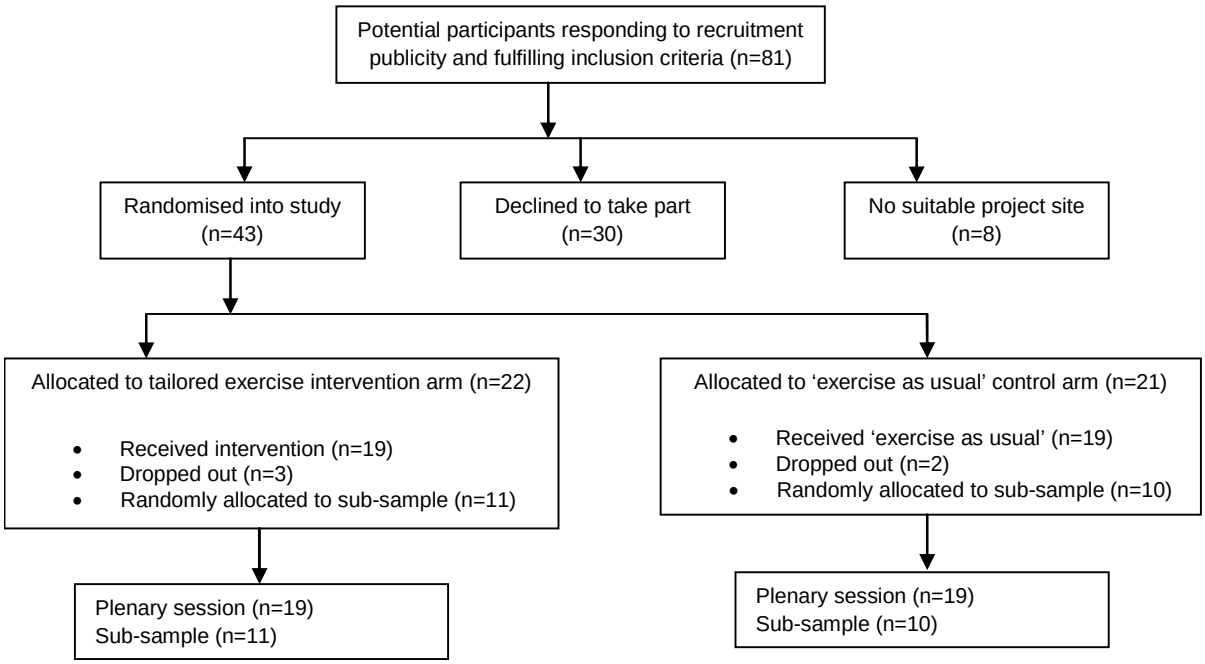

Fig. 1. Pragmatic RCT of an exercise programme for women with depression: flow of participants through study.

PROCEDURE: THE EXERCISE PROGRAMME

The project had two arms – experimental and control. There were a total of seven programmes run, with approximately four women exercising together in each, at three different sites – local authority leisure centres - in Nottinghamshire. Locations were chosen on the basis of not being associated with the university hospital or primary or secondary services, as the collaborating service user group advised that potential participants were likely to have negative feelings towards such sites arising from periods of hospitalization at these locations.

An independent researcher from the MHRN assigned the running order of control or experimental programmes to the locations using a computer generated coin toss from Random.org. The research team identified a potential research site at a local authority leisure centre, and notified the MHRN staff, who flipped a virtual coin to decide whether the first programme at the site would be experimental or control, then advised the team which programme to implement.

Participants in both the control and experimental arm experienced an initial welcome session, during which they were welcomed to the study, formal face-to-face written consent was obtained, any housekeeping and other administration were completed, and baseline measures were administered. Measures took approximately 30 minutes to administer, short forms were used wherever possible. Administration was carried out by appropriately qualified personnel from the MHRN, independent to the project, to minimise any researcher bias.

The experimental group then experienced 12 sessions of intervention, at a rate of three sessions per week for four weeks. Each session comprised; fifteen to twenty minutes of motivational support, run by a qualified rehabilitation psychologist and overseen by a qualified health psychologist; a half hour preferred exertion level exercise session run

by a qualified sports physiotherapist. Participants preferred intensity (chosen exertion level) was established using the Borg RPE scale (Borg, 1998); heart rate measures were taken using heart monitors.

The control group experienced 12 sessions of intervention, at a rate of three sessions a week for four weeks. Each session comprised fifteen to twenty minutes of healthy lifestyles education, and a half hour 'exercise –as-usual' session, designed in accordance with national guidelines and run by a qualified sports physiotherapist. National guidelines (Department of Health, 2004) currently recommend thirty minutes five times a week, but the exercise specialist advising the project felt it would be difficult to achieve this frequency without overburdening participants who may be new to regular exercise, and may risk injury to them without sufficient 'recovery' days built in to the programme.

Both the experimental and control programmes were fully manualised, and a protocol devised for both the motivational interviewing and healthy lifestyles components (see appendices H, J and K). This ensured transparency of approach, replicability and minimizes researcher effects in delivery (figure 2).

At the final exercise session all participants received a certificate recognising their achievement.

After the conclusion of the programme, both groups experienced a plenary 'thank you' session, during which outcome measures were administered. Following this there was a half hour focus group to discuss participants' experience of the programme. The focus group was recorded using a digital voice recorder. The research team, with the assistance of the collaborating NHS trusts and service user group, undertook to advise all participants of appropriate routes (based on participants home addresses) to continue exercising, be it on prescribed programmes or in voluntary sector exercise initiatives. There was an opportunity for questions from the participants, any housekeeping and other administration was completed, participants each received a £10 gift voucher as a thank you, and a close to the programme.

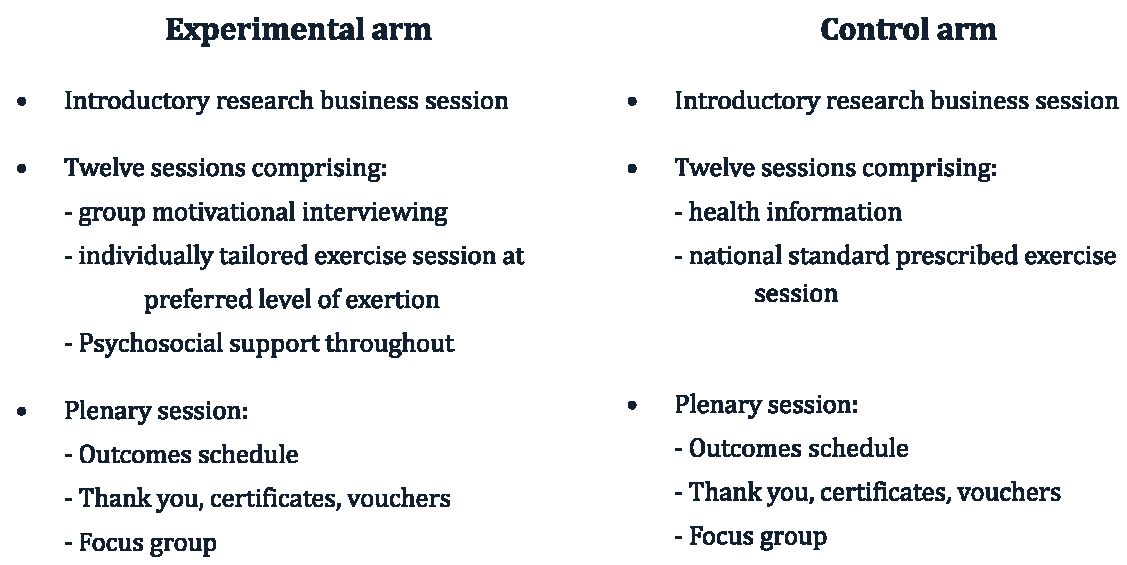

Fig. 2. Components of the experimental and control exercise programmes.

ETHICS APPROVALS AND ADOPTIONS

This study was adopted by the Mental Health Research Network (East Midlands Hub), and is registered with the U.S. National Institutes of Health clinical trials database (https://register.clinicaltrials.gov). It had R&D approval from Nottinghamshire Healthcare NHS Trust, Nottingham City Primary Care Trust and Nottinghamshire County Teaching

Primary Care Trust. The study received a favourable ethical opinion from Derbyshire Research Ethics Committee via the National Research Ethics Service (ref. 07/H0401/110).

FINDINGS

QUANTITATIVE DATA

STATISTICAL ANALYSIS

Intention-to-treat was used to compare the two groups in terms of outcomes where plenary session data were available, using *t*-tests for normally distributed continuous variables. All analyses were conducted using SPSS version 16.0.

FINDINGS

Promotion of the study and recruitment of participants occurred over a period of 14 months, between February 2008 and May 2009. The flow of participants through the study is shown in Fig. 1. A total of 81 potential participants responded to the promotional material, all of whom met the inclusion criteria (aged 45-65, female, living with depression in the community, Nottinghamshire postcode). The original recruitment target had been 140 participants, however the data were robust and the shortfall did not impact upon the statistical and clinical significance of the findings.

The 43 participants agreeing to take part were randomly allocated prior to inclusion into the experimental or control arm by a research professional unconnected to the study, using a computer generated random sequence list from www.RANDOM.ORG. In total seven exercise programmes were conducted; four experimental and three control. Table 1 details the baseline characteristics of the study groups. There was no difference in the mean age of the groups at baseline. Both groups were similar at baseline in terms of marital status, use of psychiatric medication and/or talking therapy, and level of physical activity. There was no difference in mean baseline scores for the BDI (Beck Depression Inventory II), GHQ (General Health Questionnaire), SF-12 (SF-12 Health Survey), RSES (Rosenberg Self-Esteem Scale), MSPSS (Multidimensional Scale of Perceived Social Support), and QLDS (Quality of Life in Depression Scale) between the groups. In terms of physiological outcomes, there was no difference in the mean baseline heart rate of the two groups at commencement of exercise and at peak exertion. Neither was there a baseline difference in participants' perception of exertion at these two points (RPE - Rating of Perceived Exertion scale).

Following randomisation, three participants dropped out of each of the arms of the study, failing to complete their allocated programme of exercise. In the intervention group, dropped out due to viral illness and one declined to continue, in the control group one reported the exercise as too taxing, and one declined to continue with no reason given. The intervention group attended a greater number of exercise sessions (8 out of 12 sessions) than the control group (6 out of 12 sessions), giving a mean difference of 2.3 sessions (95% CI -0.3 to 4.8). The effect size was medium (d = 0.58). An independent *t*-test showed that the difference between the conditions was significant (t = 1.781, df = 36, p = 0.0415, one-tailed).

At the conclusion of the study, data were available from 19 (86%)) of the intervention group and 19 (90%) of the control group, with additional physiological data from 100% of both sub-groups (n=11, n=10), see Table 2. Between the baseline and plenary session of the exercise programme, the experimental group reported lower BDI II scores, the mean difference in BDI II scores was -11.5, and the 95% confidence interval for the estimated mean population

difference is -20.4 to -2.7. The effect size was large, *d* = 0.86. An independent *t*-test showed that the difference between groups was significant (*t* = 2.638, df = 36, *p* = 0.006, one-tailed). There was also greater improvement in mental wellbeing as measured by the GHQ for the intervention group than the control group. The mean difference in GHQ scores was -4.0, and the 95% confidence interval for the estimated mean population difference is -6.5 to -1.5. The effect size was large, *d* = 1.08. An independent *t*-test showed that the difference between groups was significant (*t* = 3.284, df = 36, *p* = 0.001, one-tailed, unequal variance assumed). Greater improvement in self-esteem was observed in the experimental group. The mean difference in RSES scores was 3.2, and the 95% confidence interval for the estimated mean population difference is 0.3 to 6.4. The effect size was small, *d* = 0.25. An independent *t*-test showed that the difference between groups was significant (*t* = 2.045, df = 36, *p* = 0.024, one-tailed). Quality of life also improved more for the intervention group than the control group. The mean difference in QLDS scores was -5.9, and the 95% confidence interval for the estimated mean population difference is -12.2 to 0.4. The effect size was small, *d* = 0.27. An independent *t*-test showed that the difference between groups was significant (*t* = 1.902, df = 36, *p* = 0.0325, one-tailed). The mean scores for general health (as measured by the SF-12) and perceived social support (as measured by the MSPSS) improved for both groups, but there was no statistically significant difference between them.

Between the baseline and the plenary session, a reduction in perceived effort was experienced by the experimental group when exercising at their peak level, as measured by the RPE, whereas the control group experienced an increase in perceived effort. The mean difference in RPE scores was 2.4, and the 95% confidence interval for the estimated mean population difference is -0.5 to 5.2 (see Table 2). The effect size was large, *d* = 0.77. An independent *t*-test showed that the difference between groups was significant (*t* = 1.755, df = 36, *p* = 0.0475, one-tailed). Though the mean score for perceived effort at commencement of exercise improved for the intervention group and reduced for the control group, there was no statistically significant difference between them. Heart rate at commencement of the session and at peak of effort increased for both groups between baseline and plenary, but these differences are not statistically significant between groups, and reflect small improvements in physical fitness.

A within groups analysis (see Table 3) revealed that the differences across the range of psychological and social in group outcomes are explained by statistically significant improvements for the intervention group, whereas the control group scores improved less, and not significantly, with the exception of general mental wellbeing.

Between the baseline and plenary session of the exercise programme, the intervention group experienced an improvement in mood in terms of lower BDI II scores, the mean difference in BDI II score was -8.5, and the 95% confidence interval for the estimated mean population difference is -13.2 to -3.8. The effect size was large, *d* = 0.71. An independent *t*-test showed that the difference was significant (*t* = 3.769, df = 18, *p* = 0.0005, one-tailed). There was no significant improvement for the control group. However, both groups experienced improvement in mental wellbeing as measured by the GHQ. For the intervention group the mean difference in GHQ score was -4.8, and the 95% confidence interval for the estimated mean population difference is -7.4 to -2.3. The effect size was large, *d* = 1.44. An independent *t*-test showed that the difference was significant (*t* = 3.995, df = 18, *p* = 0.0005, one-tailed). For the control group the mean difference in GHQ score was -1.3, and the 95% confidence interval for the estimated mean population difference is -2.5 to -0.1. The effect size was small, *d* = 0.34. An independent *t*-test showed that the difference was significant (*t* = 2.319, df = 18, *p* = 0.016, one-tailed). Significant improvement in general health was observed in the intervention group only. The mean difference in SF-12 score was 4.0, and the 95% confidence interval for the estimated mean population difference is 0.6 to 7.5. The effect size was medium, *d* = 0.55. An independent *t*-test showed that the difference was significant (*t* = 2.435, df = 18, *p* = 0.0125, one-tailed). There was no statistically significant improvement for the control group. Self-esteem improved significantly in the intervention group and not the control group. The mean difference in intervention RSES score was 3.4 and the 95% confidence interval for the estimated mean population difference is 1.9 to 4.9. The effect size was medium, *d* = 0.63. An independent *t*-test showed that the difference between groups was significant (*t* = 4.717, df = 18, *p* = <0.0005, one-tailed). Between the baseline and plenary session of their exercise programme, the intervention group experienced an improvement in level of perceived social support, the mean difference in MSPSS score was 4.7, and the 95% confidence interval for the estimated mean population difference is -0.4 to 9.4. The effect size was small, *d* = 0.26. An independent *t*-test showed

that the difference was significant (t = 1.924, df = 18, p = 0.035, one-tailed). There was no statistically significant improvement for the control group. Finally, quality of life improved significantly for the intervention group. The mean difference in intervention QLDS score was -3.3 and the 95% confidence interval for the estimated mean population difference is -5.8 to -0.7. The effect size was small, d = 0.43. An independent t-test showed that the difference between groups was significant (t = 2.694, df = 18, p = 0.0075, one-tailed). There was no significant improvement for the control group.

Between the baseline and the plenary, heart rate at commencement of the exercise session and at peak of exertion increased for both groups, but these differences are not statistically significant, and reflect small improvements in physical ability. Though the mean score for perceived effort at commencement of exercise improved for the intervention group and worsened for the control group, but this was not statistically significant. However, at peak exertion, whilst the experimental group appeared to experience less effort (though this is not statistically significant) at plenary than at baseline, the control group experienced significantly more exertion. The difference in mean RPE score was 1.7, and the 95% confidence interval for the estimated mean population difference is -0.3 to 3.1. An independent t-test showed that the difference was significant (t = 2.684, df = 9, p = 0.025).

Research hypothesis H_1 is supported, H = A tailored exercise intervention led to better psychological, physiological and social wellbeing outcomes when compared with an intervention based on national recommendations.

Research hypothesis H_2 is supported, H Women assigned the tailored programme attended more sessions than women assigned the standard prescribed programme of exercise.

Table 1. Pragmatic RCT of an exercise programme for women with depression: baseline characteristics of study groups

	Intervention arm (n=19)	Control arm (n=19)
Mean age (years) (SD)	57.0 (9.9)	50.4 (15.2)
Marital status, *n* (%)		
Single	9 (47.4)	9 (47.4)
Married	9 (47.4)	10 (52.6)
Widowed	1 (5.3)	0 (0)
Psychiatric medication, *n* (%)		
Yes	15 (78.9)	17 (89.5)
No	4 (21.1)	2 (10.5)
Talking therapy, *n* (%)		
Yes	6 (31.6)	11 (57.9)
No	13 (68.4)	8 (42.1)
Mean strenuous exercise[1] (mins/month)(SD)	18.4 (69.1)	37.9 (89.9)
Mean moderate exercise[1] (mins/month)(SD)	513.7 (618.5)	339.5 (442.0)
Mean light exercise[1] (mins/month)(SD)	615.0 (660.5)	765.3 (466.5)
Frequency of exhausting activity[1], *n* (%)		
Often	1 (5.3)	3 (15.8)
Sometimes	3 (15.8)	2 (10.5)
Never	15 (78.9)	14 (73.7)
Mean BDI score (SD)	26.5 (10.7)	30.5 (12.0)
Mean GHQ score (SD)	8.3 (3.7)	8.8 (3.4)
Mean SF-12 score (SD)	25.9 (6.2)	25.6 (7.5)
Mean RSES score (SD)	11.3 (5.8)	11.0 (4.9)
Mean MSPSS score (SD)	47.6 (18.3)	51.6 (15.4)
Mean QLDS score (SD)	15.5 (7.9)	20.3 (8.5)
Physiological measures[2]		
Mean heart rate @ time 0 (beats/min) (SD)	87.5 (15.8)	92.8 (5.6)
Mean peak heart rate (beats/min) (SD)	109.6 (21.1)	121.3 (15.8)
Mean RPE score @ time 0 (SD)	9.2 (3.2)	8.6 (3.3)

Mean peak RPE score (SD)	10.4 (2.8)	10.5 (2.9)

[1]During the past month.
[2] Sub-sample: Intervention arm n=11, control arm n=10.

Table 2. Pragmatic RCT of an exercise programme for women with depression: primary and secondary outcomes by study arm[1]

	Intervention arm (*n*=19)	Control arm (*n*=19)	Mean difference (95% confidence interval)	*p* value
Primary outcome				
Mean BDI score (SD)				
Baseline	26.5 (10.7)	30.5 (12.0)		
Plenary	18.1 (13.0)	29.6 (13.9)		
Mean change	-8.5 (9.8)	-0.9 (6.6)	-11.5 (-20.4 to -2.7)	0.006
Secondary outcomes				
Mean GHQ score (SD)				
Baseline	8.3 (3.7)	8.8 (3.4)		
Plenary	3.5 (3.1)	7.5 (4.3)		
Mean change	-4.8 (5.3)	-1.3 (2.5)	-4.0 (-6.5 to -1.5)	0.001[2]
Mean SF-12 score (SD)				
Baseline	25.9 (6.2)	25.6 (7.5)		
Plenary	30.0 (8.7)	26.4 (7.2)		
Mean change	4.1 (7.3)	0.8 (2.8)	3.6 (-1.7 to 8.8)	0.08
Mean RSES score (SD)				
Baseline	11.3 (5.8)	11.0 (4.9)		
Plenary	14.7 (4.8)	11.5 (4.9)		
Mean change	3.4 (3.1)	0.5 (3.0)	3.2 (0.3 to 6.4)	0.024
Mean MSPSS score (SD)				
Baseline	47.6 (18.3)	51.6 (15.4)		
Plenary	52.1 (16.7)	58.1 (16.9)		
Mean change	4.5 (10.1)	6.4 (19.6)	5.9 (-5.1 to 17.0)	0.14
Mean QLDS score (SD)				
Baseline	15.5 (7.9)	20.3 (8.5)		
Plenary	12.3 (7.2)	18.2 (11.4)		
Mean change	-3.3 (3.1)	-2.1 (7.7)	-5.9 (-12.2 to 0.4)	0.0325
Mean Attendance (x/12)(SD)	8.2 (3.6)	5.9 (4.2)	2.3 (-3.14 to 4.8)	0.0415
Physiological outcomes[3]				
Mean heart rate @ time 0 (beats/min) (SD)				
Baseline	87.5 (15.8)	92.8 (5.6)		
Plenary	95.1 (18.5)	96.6(11.7)		
Mean change	4.4 (15.7)	2.0 (6.5)	1.5 (-12.2 to 15.8)	0.414
Mean peak heart rate (beats/min) (SD)				
Baseline	109.6 (21.1)	121.3 (15.8)		
Plenary	121.1 (18.2)	136.8 (29.5)		
Mean change	6.7 (17.2)	8.2 (17.5)	15.7 (-6.4 to 37.9)	0.77
Mean RPE score @ time 0 (SD)				
Baseline	9.2 (3.2)	8.6 (3.3)		
Plenary	7.9 (2.6)	9.4 (3.6)		
Mean change	-0.7 (2.0)	0.4 (1.1)	1.5 (-1.4 to 4.3)	0.144
Mean peak RPE score (SD)				
Baseline	10.4 (2.8)	10.5 (2.9)		
Plenary	9.8 (2.7)	12.2 (3.5)		
Mean change	-0.3 (1.9)	0.9 (1.7)	2.4 (-0.5 to 5.2)	0.0475

[1]Independent *t*-tests.
[2]Unequal variances.
[3]Sub-sample: Intervention arm *n*=11,control arm *n*=10.

QUALITATIVE DATA

TRANSCRIPT ANALYSIS

Framework analysis (Lacey 2001; Ritchie 2002) was used to analyse the focus group data and field notes. This thematic analysis technique was chosen because it allows for the inclusion of a priori (previously identified as relevant) and emergent concepts (e.g. unforeseen views or experiences from the participants). This method of analysis is particularly suited to health services research as it provides 'systematic and visible stages to the analysis process, so that funders and others can be clear about the stages by which the results have been obtained from the data' (Lacey 2001). The topic schedule formed the basis for the core themes in the thematic framework. A total of seven focus groups were conducted, and seven sets of field notes collected, one for each exercise programme.

CONCEPTUAL FRAMEWORK FINDINGS

The findings are presented here in a conceptual framework, organised as follows:-

Core theme A: Your experience of the programme.

Core theme B: Effect on your mood and general wellbeing.

Core theme C: Effect on your physical health.

Core theme D: What should we keep and what could we improve?

Core theme E: Would you continue?

Core theme F: Barriers to exercise.

Focus groups: B1, B2, B6 and N1 were experimental.

B5, WB1, WB2 were control.

*Focus group data is reported in normal font, data from field notes is in italics.

CONCEPTUAL FRAMEWORK

THEME A: YOUR EXPERIENCE OF THE PROGRAMME.

Group	A1 Positive experience	A2 Negative experience	A3 Feeling safe, no worries	A4 Motivation, encouragement, and sticking to it
B1€	I think there's a lot of positive spin offs from the combination of doing the physical exercise and having support to do it. ...it's helped me tremendously. Good, overall good. *They report that the exercise seemed almost too easy!* *All report feeling positive and that the social aspect is at least as important as the physical. It's seen as 'me time' and the exercise session as 'headspace'.*	I didn't find anything negative. I wasn't at any point discouraged. No, nothing negative. I haven't really found anything bad about it.	I find the positives were feeling safe, knowing someone was there to let me know what to actually do, and er, I feel that's what's great about it, because I know what I can do without worrying about it. It helped you to learn what your body can do, because I'd just get worries about that, but I'm not now. ...the way this programme has been, erm, I've no need to be frightened. I've learnt the way it goes and what to do, and how to please yourself, but before I was just thrown onto it and that really frightened me.	Because of all the encouragement and being motivated I've actually stuck to doing something three times a week which I haven't done for yonks. Because of the encouragement and enthusiasm, I only missed three out of twelve. *...a pleasant session based around what they felt they may get out of participating.* *...says 'I think that the social support coupled with the exercise is a winning combination'.*
B2€	It's been good fun... *All triumphant at the end.*	I haven't really found anything bad about it.	*Katie was nervous about the treadmill as last session she'd kept her finger on the control and made it far too fast. She was reluctant to confide in Ioannis, but did with support and he reassured her and reminded her of the set up.*	*... needed a lot of support and encouragement to try exercising a little. She managed a few minutes.* *...managed more exercise, very slow progress, but she is SO proud of herself.*

THEME A: YOUR EXPERIENCE OF THE PROGRAMME.

Group	A1 Positive experience	A2 Negative experience	A3 Feeling safe, no worries	A4 Motivation, encouragement, and sticking to it
B6€	...it's all been positive really... I've seen it as a very positive experience. ...it was erm, just positive experience. I pretended I understood the machines and things just because I was too embarrassed to ask many questions, and I wanted to look normal and together. I didn't want to look stupid, and it put a lot of pressure on me... So it's nice to have experienced this other side of being kind to myself to get a result for me, not for everyone else. *All reported being surprised that they were actively enjoying it, and ... was especially surprised to find she was actually looking forward to something for the first time in years.*	There hasn't been anything negative about it really.	I find it quite intimidating to go to the gym so to go with a couple of ladies who I know, and we're all a bit anxious and nervous, it's really nice, it gives you confidence. And you know being in a group, it meant, you know, I didn't feel embarrassed. I wanted to do something physical and I was scared of doing that, cos I've got all sorts of fears around gyms and exercise, and it was helpful to be with other women, cos I feel quite vulnerable when I go to the gym, cos there's a lot of men around, but also I think it made me feel safer. I felt secure when you turned up and gathered us together. It's helpful to go with other women who you can talk to, so you feel less exposed and vulnerable, with people you feel comfortable with. *We spent time just standing and looking at the gym and the other users, none of whom were young or fit! They would not have been confident to just stand and look and take in the surroundings if alone.*	*..admits she is surprised by how tearful she has been, because she has experienced so much support and that has been a very moving experience for her.*

THEME A: YOUR EXPERIENCE OF THE PROGRAMME.

Group	A1 Positive experience	A2 Negative experience	A3 Feeling safe, no worries	A4 Motivation, encouragement, and sticking to it
B5*c*		Can I say that the first two weeks were positive and encouraging and the second two were negative and discouraging for me. ...by the third week I was really struggling with the 40-45 minutes and being encouraged to push myself, if it hadn't been a research programme I probably would've stopped coming. I found it negative, but you and Ioannis were very professional, and not harsh or anything... I am disappointed in myself that I couldn't benefit from it, and I started being late, and didn't take it seriously and get myself there on time. And I think that I felt cross with myself that third week and then I seemed to fail. *... but not jubilant like the exp groups tend to be.* *They all felt it again today, and not elated like exp groups tend to be.* *All quite subdued.* *All got sweaty, again not jubilant but flushed and subdued.* *In the focus group ... became quite tearful, as she has not had a great experience of the control programme, and feels she has 'let herself down'.*		

THEME B: EFFECT ON YOUR MOOD AND GENERAL WELLBEING.

Group	B1 Positive effect on mood	B2 No or negative effect on mood	B3 I feel better	B4 I feel worse
B1*c*	Better. Much better. *All seemed invigorated at the end.*		I feel much better and I want to carry it on. I didn't have to perform to a level or time, it , it, spilled over into life generally, and over 4 weeks it's made such a difference, to not put myself under pressure and to not feel that life is running away with me. I think what's good for your body is good for your mind too. Better. Better.	
B2*c*	I seem a lot happier.			
B6*c*	I feel more confident in my emotional self. I do think it's helped with my mood actually. I know it's had a positive effect.		Better.	
N1*c*	I think it's helped with my mood. I feel positive and rewarded in the exercise, and it's coping with the illness isn't it, instead of just sitting and moping in that rut. I feel more positive...	Better physically, but my mood, not sure.	I feel energised. Better on the whole, I got over my fear and integrated in a group. And I feel healthier also, I lost a kilo. Better physically, but my mood, not sure. I have slept better.	
B5*c*		...my mood is depressed by my failure. I just found it hard.		I don't feel better, I feel worse.
WB1*c*		I'm not sure that it has to be honest.	Initially I felt tired after the exercise, then I felt better for having done it. It's helped a little bit.	
WB2*c*	A little bit.			

THEME C: EFFECT ON YOUR PHYSICAL HEALTH.

Group	C1 Positive effect	C2 No or negative effect	C3 Physical confidence	C4 Pacing myself
B1€	It helped you to learn what your body can do, because I'd just get worries about that, but I'm not now. Yes it's helped me. I thought I had energy, but I have a lot more now. I don't feel so tired, I feel I can cope more, I just feel better in myself. It's given me a lot of confidence in what I can do physically. Physically it's done me enormous good, enormous. ...definitely a bonus. *...all the ladies feel they have improved physically*.		It helped you to learn what your body can do, because I'd just get worries about that, but I'm not now. I've learnt the way it goes and what to do, and how to please yourself... It's given me a lot of confidence in what I can do physically.	Instead of setting myself goals all the time that some days I couldn't reach I learnt to take it at my own pace and deal with things as and when I could rather than trying to do all the things that I couldn't. It's not that I hadn't tried to exercise on my own, I have done, lots of times, but the tension that I had whilst I've been low, every bit of physical work has felt like I've run a marathon, and I had all the aches and pains and tiredness, muscles hurt, but the technique that we've been taught to not over do it and do what you're comfortable with, I've gone home with no aches, it's marvellous. Things I do now I pace myself.
B2€	I have felt a lot better in myself, I can walk a lot better and I'm breathing better. I've been told my face is slimmer too. *...enjoyed the tread mill and were elated afterward.*		*All set off with gusto, looking forward to using their bodies and feeling they have 'a right to be there'.*	
B6€			I feel more comfortable going to the gym. I feel more confident in my physical self.	I think I wanted to go mad and come out looking like a super model, but Ioannis and you did very well to clear my mind of all that and get me to focus a bit more on emotional wellbeing. (previously) I pushed myself too hard on the machines and I thought I could use them as a way of punishing myself, and no-one would notice really. So it's nice to have experienced this other side of being kind to myself to get a result for me, not for everyone else.

THEME C: EFFECT ON YOUR PHYSICAL HEALTH.

Group	C1 Positive effect	C2 No or Negative effect	C3 Physical confidence	C4 Pacing myself
N1*c*	...I feel healthier also, I lost a kilo. Better physically... I have slept better. I'm eating better. *... reported that she had been surprised having dragged herself along yesterday to having been energised by the session and then sleeping really well that night.*		I am more confident in my physical self. I got some confidence.	
B5*c*		No physical difference.	...by the third week I was really struggling with the 40-45 minutes and being encouraged to push myself...	
WB1*c*	Initially I felt tired after the exercise, then I felt better for having done it. It's helped a little bit.			
WB2*c*		I found it quite tough at first, my knees hurt.		

THEME D: WHAT SHOULD WE KEEP AND WHAT COULD WE IMPROVE?

Group	D1 I like being in a group	D2 Length of sessions	D3 Exercise modality and environment	D4 Feeling secure
B1*c*	Having somebody else in important, yeah. Yeah you keep each other coming. I used to go to the gym a couple of years ago and due to illness and things I stopped going and I found it very difficult. I failed to go back because I just couldn't get the impetus to go, once I was there it was fine, it was just getting there, but knowing I'm coming to a group and there's other people going to be there it does help. *The ladies talked enthusiastically about anticipated benefits and personal goals.*	Just right, maybe another 10-15 minutes exercise, the more I had the more I wanted! Pretty good, maybe would like to extend the exercise at the end of the programme.	A different exercise would have more appeal, extra to offer for me. I'd try everything in the gym, and I'd like to get stuck straight in. I think I'd find the cross trainer more absorbing. I'd want something that absorbs my mind more, less automatic. *Explored 'how to provide the right prescription exercise'. They said: Support with practicalities like machinery, where to change, what to wear. Want structure of an organised visit, to help with organising themselves and so not walking in alone.*	I think the affirmation is important, so don't get rid of it. Gyms and changing rooms bring back all these difficult memories so being reassured constantly was very important, being reminded to be kind to myself. Cos if I'd gone on my own I'd have been using it as a form of self-harm to punish myself. It's been very healing. *Explored 'how to provide the right prescription exercise'. They said: not a special session, open to all but for 'timid' users, lots of support and encouragement and monitoring =safe. Support ... with feelings of fear, anxiety, ambivalence. Want structure of an organised visit so not walking in alone.*
B2*c*	The group stuff makes you more of a team. Well I think it probably helps that people are in a similar situation.	I've done a bit more on some days than others, so being able to carry on a bit would be good.	I prefer it when the gym's quiet.	

THEME D: WHAT SHOULD WE KEEP AND WHAT COULD WE IMPROVE?

Group	D1 I like being in a group	D2 Length of sessions	D3 Exercise modality and environment	D4 Feeling secure
B6*c*	...we've got to know each other which is good. I find it quite intimidating to go to the gym so to go with a couple of ladies who I know, and we're all a bit anxious and nervous, it's really nice, it gives you confidence. Well, I think we all got to know each other a bit better and it was erm, just positive experience. And you know being in a group, it meant, you know, I didn't feel embarrassed. I would have felt a lot worse if it hadn't been for you two. We're all in the same boat. ...it was helpful to be with other women, cos I feel quite vulnerable when I go to the gym, cos there's a lot of men around, but also I think it made me feel safer... I really enjoyed the camaraderie. We were all having a bit of a laugh at the same time. And it's socialising in a safe way, cos we're not saving each other, or rescuing each other, or taking each other's problems on board, but we have a bit of chat, and are open, and distracted from our problems. I went to a yoga class, and you look at every one and they all seem to have got all the gear and know what's what, even though it's all women. It's helpful to go with other women who you can talk to, so you feel less exposed and vulnerable, with people you feel comfortable with. *...but ... became very tearful. They supported her very kindly.* *Had to tell them off for being too chatty in the gym and not concentrating enough!* *All 3 say being in group has been vital, and the chance to make new friends.*	I want longer and more variety.	I want longer and more variety. Well, I wondered if it would be possible to use some of the different equipment so you rotated perhaps.	

THEME D: WHAT SHOULD WE KEEP AND WHAT SHOULD WE IMPROVE?

Group	D1 I like being in a group	D2 Length of sessions	D3 Exercise modality and environment	D4 Feeling secure
N1*c*	I'm really pleased and proud of what I did, and I wouldn't have done it without the fact that I was in a group, and the encouragement and bonding of the group and everyone in it was very helpful, all of us chatting and going in together. It helped knowing it was group of ladies with the same problem as I do, it helped. *All a bit nervous but reassured by group. All 3 enjoyed it and seem relieved at the end. Confident about next time as long as they've got each other.*	It was just enough for me I think I'd have struggled if I'd gone on any more, cos I was really somebody who didn't do any exercise as such. Even that first session actually, of the first time on a treadmill. I think in the penultimate one I did too much and extended myself trying to increase the gradient, and then on the last one I had to modify that. Ok for me in gradually increasing the time, because it gave me time to get used to the ladies in the group, and doing the exercise in the gym. ...fifteen minutes was quite enough for the first day of going, scared!	I liked it. I liked the walking machine, I wouldn't change it.	
B5*c*		...not being told how long to do, let me choose, cos some of the time it was too long.	I've got visions of a wonderful gym with very positive affirming images and music, none of this sexy unattainable physiques prancing around on screen and music blasting in your earholes at a volume that you can't choose. And always being given a lovely choice of clothing so you don't have to worry what to put on. But realistically it's more helpful to find out what the local gym is like to see if I could use it, so I wouldn't change that, but I hate that music. ...maybe other machines now, diversity.	
WB1*c*				
WB2*c*		Last week a bit too long.		

THEME E: WOULD YOU CONTINUE?

Group	E1 I want to continue	E2 I would not continue
B1*C*	I feel much better and I want to carry it on. I'm obviously going to carry it on. Definitely. Yes. I'm going to go twice a week now. I got my card on Friday!, it will keep some structure in my life. Come with me on a Thursday morning.	
B2*C*	I'm going to change my day I come in so I can go.	
B6*C*	Yes I did like it, I would carry on most definitely. I would. It's made me want to do more. Yes I would.	
N1*C*	Yes. I would. So would I. And me And me! Yes, but probably only twice a week.	
B5*C*		I only did it because it was a research project, I wouldn't have done it on my own. No.

THEME E: WOULD YOU CONTINUE?

Group	E1 I want to continue	E2 I would not continue
WB1*c*	Yes if I knew I had someone to come to and meet up with.	No, it's unlikely that I'll carry on. I want to, but I shouldn't have thought so. Not three times a week, no.
WB2*c*		I don't think I'd manage it without help.

THEME F: BARRIERS TO EXERCISE.

Group	F1 Exercise environment	F2 Exercise modality	F3 Motivation and logistics	F4 My significant others' attitude
B1*ϵ*	If you put mirrors on every wall, and filmed me, I wouldn't go again. I wouldn't like mixed groups, though I'm much more confident now.	If you kept me doing the same thing, that would put me off, if I couldn't use different machines.	*...the ladies focused on their own goals and barriers.*	*Partners who wish to limit self-confidence as a means to keeping power was a core theme.*
B2*ϵ*			Getting bored.	
B6*ϵ*			You'd have to plan it. The cost.	Justifying the time.
N1*ϵ*	*... doesn't want to exercise alone, used to be in a group and it folded.* *... likes groups.* *... really does not want to do it alone, likes groups.* *Today they seemed to begin to enjoy it, and chatted throughout.*		Money. Finding the time. *She has exercised in the past but it got too expensive.* *... has to have a formal timetable or she won't do it* *Her main barriers would be loneliness and lack of funds.*	What do you want to do that for? That's not for you.
B5*c*			Money, cost. The music being consistently so high.	
WB1*c*				
WB2*c*			Health, illness, otherwise no. Oh, maybe money.	

SUMMARY OF QUALITATIVE FINDINGS

The women in the experimental arm reported a positive experience of the programme, and also stated that they had not encountered anything negative in the programme. In contrast, the control arm reported some negative experiences of their programme, and did not report having had a positive experience. The experimental arm reported that the positives were feeling safe and supported, and feeling motivated and encouraged, and feeling part of a group. The control arm did not report any of these positives. The experimental arm reported a positive effect on their mood, or 'feeling better'. The control arm made no reports of benefit to mood. Whereas some of the experimental arm participants reported physical improvement, the control arm reported physical discomfort. On the topic of what was good about the programme, and what could be improved, the experimental arm overwhelmingly stated being in a supportive group as a good feature. Some women reported that they would like the opportunity to exercise for a little longer, or try different forms of exercise, as they progressed within the programme. When asked if they would continue on the programme the majority of women in the experimental arm said yes, whereas the control arm stated that they would not, or that it would be unlikely. In terms of barriers to exercise, the most often stated obstacles were doing it alone, cost, prioritising the time, and other's attitudes.

DISCUSSION

This study aimed to investigate the effect of a tailored programme of low effort physical activity and psychosocial support on global well-being in a community-based sample of women living with depression, and to compare the tailored programme with a commonly prescribed programme of exercise-as-usual. We also sought to capture relative attendance rates between the two groups, in order to discover if a tailored programme would encourage more frequent attendance. Finally, we sought to explore the participants' experiences of the programme. The latter is important in interpreting the quantitative findings of the study, but also because there is a paucity of qualitative studies of exercise as a treatment for depression (MHF, 2004).

Analysis of the quantitative data showed that participants in experimental arm of this study experienced a statistically significant greater improvement in a number of the constructs of wellbeing than participants in the control arm, though improved scores were seen for both groups. These were depression, mental health, self-esteem, and quality of life. No difference between the groups was found for physical health, heart rate and perceived social support. It is possible that the duration of the programme (one month) was not sufficient to produce significant physiological improvements through exercise, particularly for the experimental arm at low-effort levels, effects may have been seen with another two or three weeks of input Alternatively, this may be a type 2 error due to smaller than hoped for sample size.

. Certainly the frequency of three times a week falls below the current government recommendation of five times a week, but it was felt that this new standard would be unachievable by the participant group, coming from a sedentary lifestyle and volunteering their time, so the previous standard was applied. In terms of social support, both arms exercised in a group of peers, and both arms stated this as very valuable to them, this is likely to have had some bearing on perception of social support. The experimental arm participants attended significantly more exercise sessions than the control arm women, in the focus groups they made it clear that they felt the rewarding nature of the experience had encouraged them to attend, when perhaps they may previously have failed to do so. It is clearly important that exercise programmes intended for delivery to people with mental health problems are specifically designed to be acceptable and acessible to this group. Existing research literature concurs with these findings of this study, that where exercise interventions are specifically tailored to be acceptable to people with mental health problems 'contrary to common opinion, adherence ... is at least similar to other forms of treatment. In one study where physical activity was offered as part of psychiatric services, adherence was comparable to that of the general population' (DoH 2004).

There was no difference between the groups in perceived exertion at the commencement of the plenary exercise session, but a significant difference at peak exertion. Perceived exertion represents the team's indicator of how much

effort participants feel they are making, and how comfortable they are in the exercise. The design of the intervention involves a very low-effort, comfortable experience for the experimental arm, and a less comfortable, more effortful experience for the control arm. These data reveal that this was indeed the case, indicating that the two programmes were pitched accurately in terms of reflecting an 'exercise-as-usual' versus 'low effort' experience. The similarity in scores at the commencement of the session shows that any difference is due to the exercise experience, and not to differences in individual interpretation of effort. Certainly this is evident in the qualitative data, with experimental arm women expressing surprise and relief at being instructed to take it slow, and control arm women expressing discomfort, or notions of hard work.

Upon unpacking the quantitative data further and analysing within group differences, it is apparent that most of the difference between groups is due to large gains for the experimental arm and not for the control arm. The experimental arm was observed to have made statistically significant improvements across all of the scales chosen to represent wellbeing depression, mental health, physical health, social support and quality of life), the control arm improved significantly only for general mental health, though again scores were all improved to some degree as one would expect with any intervention. These gains in the control arm however, were not of the same magnitude and, the focus group data reveals, not made through a particularly positive experience and not conducive to lasting change in behaviour. Interestingly the difference in social support was revealed to arise solely from significant improvement in the experimental arm. This can be unpacked using the qualitative data which reveals that just being in a group is seen as valuable, but being in a supportive, encouraging, facilitated 'team' is more valuable.

Themes evident in the focus group data from the experimental arm validated the design and delivery of the specially designed exercise programme:

- My experience of the exercise programme was positive and rewarding

  I feel positive and rewarded in the exercise and it's coping with the illness isn't it, instead of just sitting and moping in that rut.

- Participation in the programme has had a beneficial effect on my mood
- Participation in the programme has had a beneficial effect on my physical health

  I feel more confident in my physical self and my emotional self. I do think it's helped with my mood.

- I feel generally better for having taken part

  I feel energised.

- If I could continue to do exercise sessions like this on a regular basis I would

  Yes!

Existing literature (Biddle 2001) indicates that the psychological benefits of exercise, outcomes such as 'feeling better' and enjoyment, assist long-term motivation. The women in the tailored programme felt 'better' and enjoyed their exercise experience, this is important in helping them to maintain a longer term exercise routine and stay motivated. Many of the women in our study had not previously explored exercise as a treatment or adjunct to treatment, and were delighted to discover the benefits. We can conclude that carefully targeted programmes that maximize psychological benefits make exercise a sustainable treatment choice. The evidence base is unanimous in the opinion that currently 'exercise is seldom recognized by mainstream mental health services as an effective intervention in the care and treatment of mental health problems' (Callaghan, 2004, MHF 2004). Exercise promotion needs to be part of every care package (and tailored specifically to this group based on available evidence and user input). Robson and Gray (2007) suggest that this process should begin when the service user first comes into contact with mental health services. The Chief Nursing Officer's Review of Mental Health Nursing recommends that MHNs 'actively engage in health promotion strategies ... for example by encouraging physical exercise' (DoH 2006), Gray and Robson (2007) also point out the opportunity for MHNs to play a significant role in this arena. Some of the women in this study reported being offered exercise on prescription as a method of weight maintenance (weight gain is a side-effect of many anti-

depressants), but not as a treatment of depression. The majority of GPs do not currently prescribe exercise as a treatment for depression or recognize its value (Mental Health Foundation 2004). The Mental Health Foundation (2004) recommend that GPs with access to exercise referral schemes should offer all patients presenting with mild or moderate depression the opportunity for referral to that scheme as part of their treatment plan. Many of the women who participated in the study had used anti-depressant medication and been dismayed by the unpleasant side-effects. Conversely, no participants reported unpleasant side-effects as a result of engaging in exercise, other than occasional reports of mild aches from using dormant muscles, yet positive benefits were experienced.

Themes evident in the focus group data revealed four key elements in designing and delivering an appropriate intervention to this group.

- The facilitated group nature of the sessions was vital:

  I'm really pleased and proud of what I did, and I wouldn't have done it without the fact that I was in a group, and the encouragement and bonding of the group and everyone in it was really helpful, all of us chatting and going in together.

- The opportunity to explore the exercise environment was invaluable, reduced anxiety, and increased comfort:

  They look to be the same age as us!

- My significant others' negative attitudes to me exercising is an obstacle to belief in change

  What do <u>you</u> want to do that for?

- Money and scheduling might be the barriers to me doing exercise sessions like this on a regular basis

Our findings reveal that the social aspect of an exercise programme is valued by women with depression. However, as the government report 'Five a Day' points out 'little is known about the potential of physical activity to alleviate social exclusion or to enhance social outcomes; it is likely that the impact … is greater than the limited evidence base suggests' (DoH 2004). Clearly further research exploring the potential social benefits and how these could be maximized is required. As 'Five a Day' (DoH 2004) suggests, there is a potential for physical activity programmes to be utilized as part of a wider ranging strategy to tackle issues such as social exclusion. The majority of participants reported surprise at discovering that other people exercising were 'the same as us', the experience was seen as normalizing, as opposed to stigmatizing as so many gym users 'are the same as us' it was seen as a normalising experience, rather than stigmatizing, which was their experience of other treatments such as medication and talking therapy. Affordability was cited as a barrier to regular exercise, by women considering funding the treatment themselves, but in fact, exercise offered on script is a very affordable choice for commissioners (MHF,2004). Participants highlighted the importance of belief when they reported that they felt that their families' attitude to their exercise regime could influence their experience, and their potential for benefit. Belief in change appears to play a central role in the benefits derived from exercise and in maintenance of a life-time routine. It seems paramount therefore that participants have adequate emotional support, especially in the initial stages of establishing an exercise habit, and equipped with strategies for overcoming obstacles and maintaining the changes in their lifestyle. One of the most fundamental ways in which this study supported the participants was to make the opportunity to explore the exercise environment and physically escort participants over the threshold (it had been suggested in the previous pilot study that this may be an area of real challenge to the participants). Women reported this aspect of the design as being invaluable to them in terms of reducing their anxiety and promoting belief that change was possible. Support of this type was gradually withdrawn as the experimental groups established their own support mechanisms and grew in confidence. This is a good example of a very specific way in which a programme for this client group may need to be structured to facilitate attendance in the early stages of establishing an exercise routine.

CONCLUSIONS

A tailored exercise programme demonstrated significant benefit across a range of psychological, social and physical outcomes constituting 'health in women living with depression'. The women achieved these gains via a positive, comfortable experience.the positive nature of the experience encouraged regular attendance.Delivering an intervention informed by service users and responsive to them ensured the success of the programme.

RECOMMENDATIONS

Several areas key to improving the wellbeing of women living with Depression through exercise participation coupled with psychosocial support have been identified in this study. Recommendations are made regarding these areas, encompassing general principles for delivery and design of exercise interventions and for further research.

PROVISION OF EXERCISE INTERVENTIONS FOR PEOPLE WITH MENTAL ILLNESS

- Mental health service providers should include exercise promotion in each care package for women diagnosed with Depression.
- All GPs should offer women presenting with mild or moderate depression the opportunity for referral to exercise programmes tailored to their needs.
- It needs to be clear to the target group that the exercise offered is specifically tailored to their needs.
- Prescribed exercise programmes need to focus on improving, and measuring improvement in, health and social care outcomes.
- Provide primary care practitioners, MHNs and local authority leisure centre staff with basic training and manualised guidelines for recruiting and supporting depressed women in exercise activity, continued attendance without dropping out, and return to exercise after periods of crisis.

DESIGN OF EXERCISE PROGRAMMES

- Exercise programmes should include service user involvement in design and delivery, and systematically collect and respond to feedback from users.
- Exercise programmes designed for women living with Depression need to be structured to facilitate attendance in the early stages of establishing an exercise routine.
- Exercise programmes must pay attention to the value of exercise as a normalizing experience that promotes social inclusion, focusing on group exercise in a supportive friendly environment.
- Exercise programmes should be evaluated against a range of wellbeing outcomes with special reference to continued attendance as a discrete measure of perceived benefit.

RESEARCH ON EXERCISE AND MENTAL HEALTH

- Further qualitative research exploring what makes for an acceptable, accessible exercise programme is needed. A longitudinal study evaluating the longevity of lifestyle change and benefit, as well as issues around returning to exercise following a crisis is recommended.

- Further research focusing on how the social mechanisms of support, interaction and affiliation are linked to exercise adherence is needed.

- There is a need also for more focus on HOW the social mechanisms of support, interaction and affiliation might work within exercise programmes.

DISSEMINATION AND FURTHER RESEARCH

ACADEMIC DISSEMINATION

- The findings have been presented at interim and completion at the Network for Psychiatric Nursing Research conference:

  Khalil E, Callaghan P, Morres I (2009). Measuring the benefits of exercise to depressed women: quantitative vs. Qualitative findings. The 15th International Network for Psychiatric Nursing Research (NPNR) Conference, Oxford, September 2009.

  Khalil E, Callaghan P (2008). The potential of psychosocial support in enabling depressed women to benefit from physical activity. The 14th International Network for Psychiatric Nursing Research (NPNR) Conference, Oxford, October 2008.

- A paper is being drafted for publication in an international academic journal. The Nursing Times have approached the team for a practice-based article, which is in draft. A further practice-based article has been written for the Depression Alliance publication 'Stepwise'.
- The findings will be presented locally within the School of Nursing and the wider university to mental health and public health audiences, assisted by the Mental Health Research Network.

OUTREACH

- Press releases detailing the project and findings were sent out at local and national level, and also trailed on the University's home webpage:

  Khalil E, Rayner E (2009). Running away from depression. Press release and feature article on UoN home webpage, http:/communications.nottingham.ac.uk/News/Article/Running-away-from-depression.html, 10/02/09.

  Khalil E, Rayner E (2009). Walking back to happiness. Press release and feature article on UoN home webpage, http:/communications.nottingham.ac.uk/News/Article/ Walking –back-to-happiness.html, 09/10/09.

- Findings will be posted in lay-language on the project website: http://www.nottingham.ac.uk/nursing/exercise_wellbeing/index.php
- An information leaflet detailing the findings has been sent out to all of the participants and collaborating primary and secondary services (refer to appendix G).
- The women who participated in this study are those commonly seen in GP surgeries up and down the country. The researchers intend to make GPs and PCTs aware of the benefits of adding this to the range of services they make available to women living with depression through a process of educational outreach meetings in the

coming months. Educational outreach visits and interactive educational meetings within local and regional health communities and service user groups are already being conducted.

FURTHER RESEARCH

A pragmatic randomised controlled trial of a preferred intensity exercise programme to improve physiological and associated psychological, social and wellbeing outcomes of young people living with depression is the next planned study in this sequence.

In addition, a multi-site trial of the tailored exercise programme for women with depression is planned, utilizing the work described here as a pilot study.

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APPENDICES

A. RECRUITMENT FLOW CHART

B. PROMOTIONAL FLYER AND WEBSITE

C. GP RECRUITMENT INCLUSION FLOWCHART

D. MHRN PROJECT INFROMATION SHEET

E. PROMOTIONAL PRESS RELEASE

F. FOCUS GROUP TOPIC GUIDE

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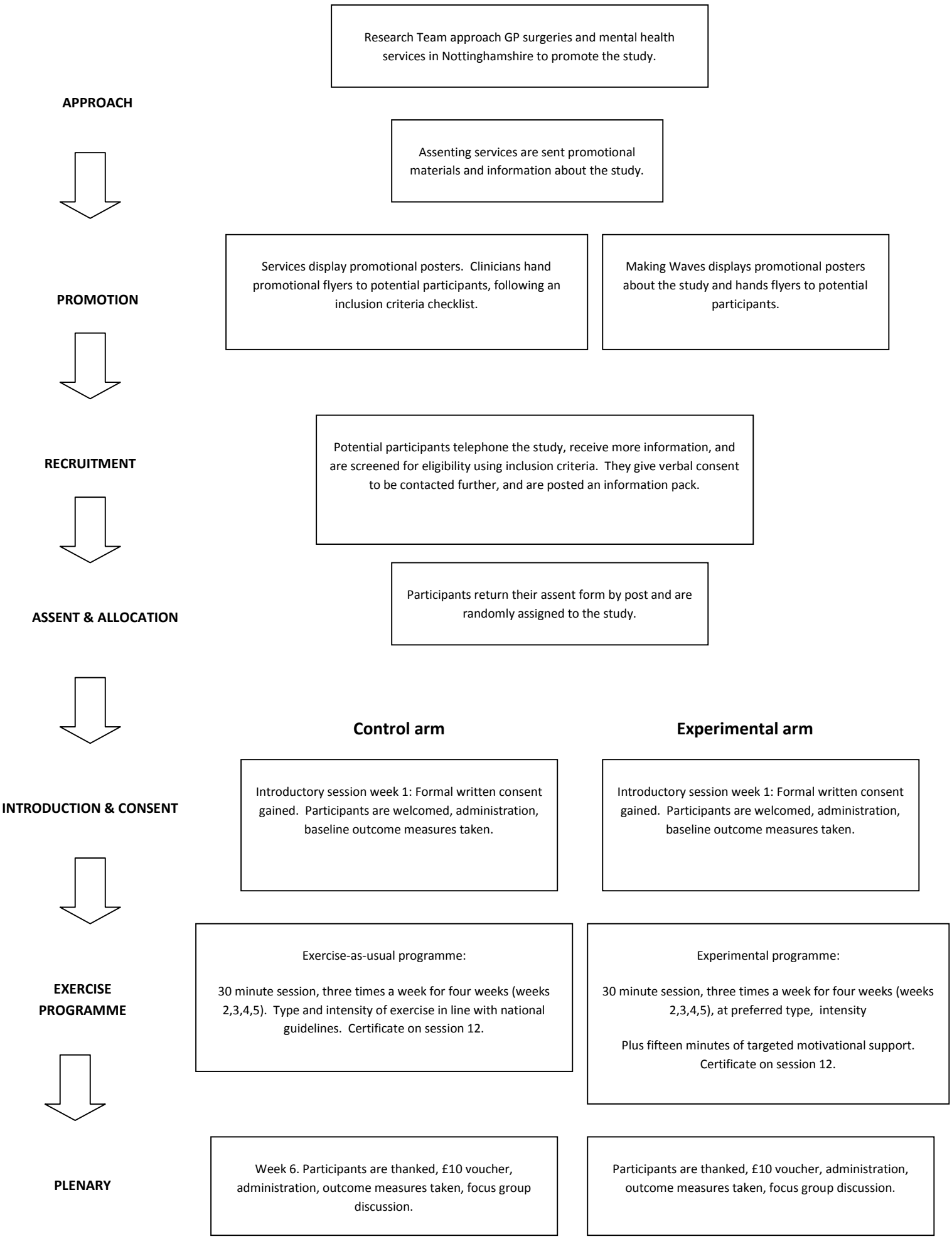
H. PROGRAMME PROTOCOL

J. EXERCISE PROTOCOL

K. MOTIVATIONAL INTERVIEWING PROTOCOL

APPENDIX A. RECRUITMENT FLOW CHART.



APPENDIX B. PROMOTIONAL FLYER AND WEBSITE

The University of Nottingham

Women with depression – our exercise study needs you

Want to feel fitter, healthier and happier?

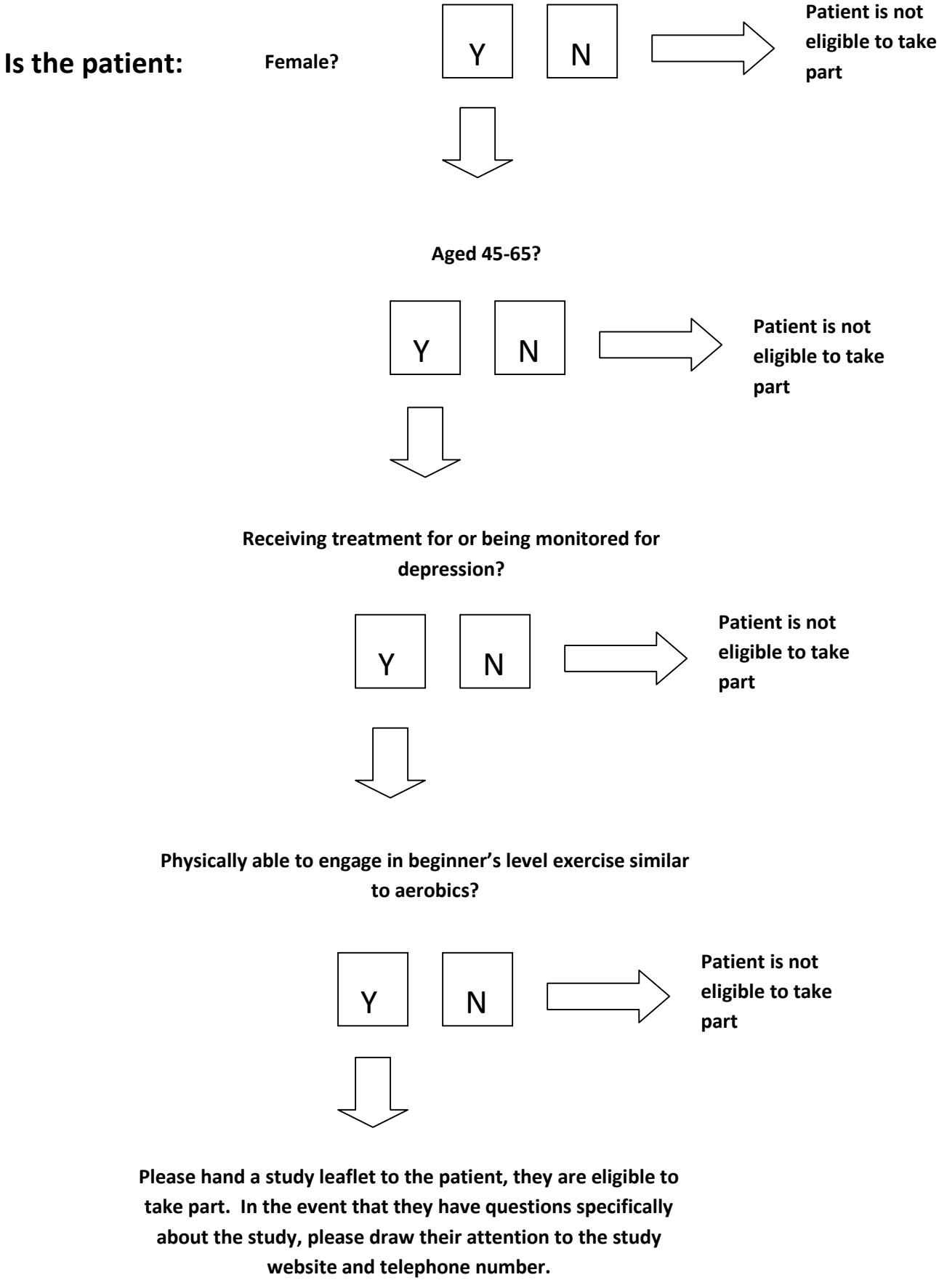
Visit our website http://www.nottingham.ac.uk/nursing/exercise_wellbeing

Or telephone Liz on 07504 532429 between 10 a.m. and 4 p.m.

We are running a free four week exercise programme as part of a research study. It will be friendly and fun, exercising in a small group of women, led by experts in physical activity for depressed people.

If you are a woman aged 45-65, resident in Nottinghamshire, depressed, and physically able to do beginners level exercise, you can take part.

C. GP RECRUITMENT INCLUSION FLOWCHART



Exercise and Well-Being Study

The Project

- Involves a free four week exercise programme as part of a research study. It will be a friendly and fun experience, exercising in a small group of women, led by experts in physical activity for depressed people.
- Open to women resident in Nottinghamshire, depressed (no formal diagnosis required), and physically able to do beginners level exercise.
- This project is part of the Mental Health Research Group at the School of Nursing, University of Nottingham.
- Funded by the Burdett Trust for Nursing.
- The project has approval from the Research Ethics Committee and Research and Development in Nottinghamshire Healthcare NHS Trust and Nottingham County Teaching Primary Care Trust.

Why are we doing the study?

Exercise is good for us, for our mood, our physical health and our social wellbeing (Mental Health Foundation, 2005).

Our previous research found that women with mental illness don't do much exercise. These women said that they found exercise on prescription from the G.P. to be a negative experience. They said that they wanted to be able to exercise to help control their weight, boost their mood and help them feel better physically.

Using motivation and providing effective support in a behavioural intervention such as our exercise programme can be helpful to people with mental illness so we have included motivational support in our programme. The success of an intervention can be influenced by careful targeting to suit the participants' needs and abilities. Furthermore, exercise may be more beneficial for depressed people if it is at the participant's preferred intensity (chosen level of physical exertion). For these reasons our exercise programme will be carefully matched to individual needs and abilities. A specially designed exercise programme such as ours, has the potential to benefit service users better than exercise on prescription.

Developing and evaluating an exercise programme that people with mental illness can use successfully is important, because improving the physical health of people with mental illness is a national priority (Department of Health 1999), and because exercise also improves mood and social wellbeing, which is of particular relevance to this group of people.

Benefits of participating

- ➡ A fun and easy free four-week exercise programme in a friendly environment alongside other women. The programme will be led by experts in exercise for people with mental and physical health problems.
- ➡ Travel costs are reimbursed.
- ➡ A certificate of achievement and a £10 thank you voucher at the end of the programme.
- ➡ Advice about how to carry on exercising.
- ➡ The chance to make a contribution to knowledge about what works for women with depression and to get personal views and opinions heard.

The Study Team

Professor Patrick Callaghan *(Principle Investigator)*

Patrick is Professor of Mental Health Nursing at the University of Nottingham and Nottinghamshire NHS Healthcare Trust. He heads a research programme designed to enable people to recover from mental distress, leading on service evaluation, testing the effect of psychosocial, interventions on health and well being and investigating links between mental health nursing and service user outcomes.

Liz Khalil

Liz is an experienced researcher at the University of Nottingham School of Nursing, she has been working in the mental health research group for four years. Liz has carried out a number of projects about the effectiveness of mental and physical health services for women. Liz is especially interested in the wellbeing of women with mental health problems like depression, and in the positive effects that exercise can have.

Ioannis Morres

Ioannis is the exercise consultant and research associate of the programme. Ioannis has extensive experience in physical activity interventions in mental health care including planning, developing and research. Since 2003 he has been investigating preferred intensity of exercise as an intervention for people with depression.

To volunteer or for further information

To volunteer please contact ***Liz Khalil***, Monday to Friday between 10am and 4pm on ***07504 532429*** or via the website***:*** ***http://www.nottingham.ac.uk/nursing/exercise_wellbeing***

For further information please contact ***Liz Khalil*** at the University of Nottingham on ***(0115) 8230873*** or email ***Elizabeth.Khalil@nottingham.ac.uk***

This study is assisted by the NIHR

Mental Health Research Network

East Midlands Hub
UK Mental Health Research Network

NHS
National Institute for Health Research

E. PROMOTIONAL PRESS RELEASE

Running away from depression

Fri, 06 Feb 2009 11:06:00 GMT

A new study into how exercise can help women overcome depression is looking for volunteers to step on to the treadmill.

The value of sport and exercise for people who are depressed is well-documented but there is evidence that gym sessions prescribed by doctors are generally regarded as unhelpful and lonely by women sufferers. Now scientists at The University of Nottingham's School of Nursing have come up with a new type of exercise programme which they believe will be much more effective at banishing the blues.

It's targeted at women who are in a vicious circle of depression perpetuated by low levels of physical activity, increasing health and weight problems, low self-esteem and lack of motivation. Previous research by the School of Nursing has found that the standard prescribed exercise programmes, usually gym sessions, don't work for this group of sufferers as they are left to arrange them and carry them out alone. The researchers have now come up with a new system of 'mentored' exercise which they think could provide the key to breaking the cycle of depression.

Click here for full story

They're looking for up to 40 women with depression living in the Nottingham area to take part in a randomised trial of both the standard exercise programme, and the new type of individually-tailored programme which includes personal motivational support from mental health professionals and exercise consultants. The trial classes are being run for four weeks at a time, at the Rushcliffe Leisure Centre in West Bridgford, Chilwell Olympia and Bramcote leisure Centres in Beeston and The Grove Leisure Centre in Newark.

One sufferer, Margaret from Beeston, who has already joined the research project said: "I think that the social support coupled with the exercise is a winning combination". Another participant, Maggie from Nottingham, said: "It makes me feel energised and gives me a real boost".

Lead researcher on the team, Elizabeth Khalil, said: "We believe this new approach could make a huge difference to the success of future prescribed exercise programmes. It gives women a chance to make a contribution to knowledge about what works for those with depression and also to get their personal opinions heard."

Developing and evaluating an exercise programme that people with mental illness can use successfully is important because improving the physical health of people with mental illness is a national priority set by the Department of Health. The research is being funded by the Burdett Trust for Nursing, and has been adopted by East Midlands hub of the Mental Health Research Network, part of the National Institute for Health Research and the UK Clinical Research Network.

Women who suffer from depression, live in Nottinghamshire and are physically able to do beginner level exercise can phone the project hotline on 0115 823 0873 to find out about volunteering for the trial, or visit the website http://www.nottingham.ac.uk/nursing/exercise_wellbeing/index.php.

F. FOCUS GROUP TOPIC GUIDE

Title of Project: **Pragmatic RCT of an exercise programme for women with depression**

Names of Researchers: Professor Patrick Callaghan, Elizabeth Khalil, Ioannis Morres.

1. **What was your experience of the exercise programme?:-**

    - **What was positive or rewarding?**
    - **and negative or discouraging?**

2. **How has participation in the programme affected your mood?**

3. **How has participation in the programme affected your physical health?**

4. **Do you feel generally better, worse or the same for having taken part?**

5. **Please comment on the length of the sessions: too long?, too short? About right?**

6. **What could we change about the exercise programme to improve it?**

7. **If you could continue to do exercise sessions like this on a regular basis would you?**

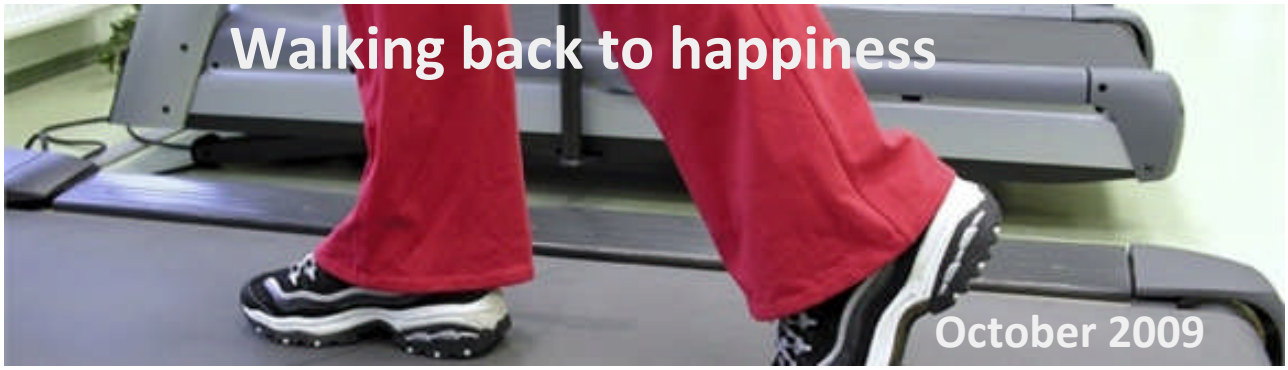
8. **What might be the barriers to you doing exercise sessions like this on a regular basis**

9. **Any other comments or questions?**

G. LAY FINDINGS INFO SHEET

The University of Nottingham

NHS National Institute for Health Research



A unique exercise programme which has been proven to help women living with depression has been devised by researchers from The University of Nottingham.

The programme is a result of a two year research study in the School of Nursing, Midwifery and Physiotherapy. Its mission has been to help women who are living with depression, characterised by low levels of physical activity, increasing health and weight problems, low self-esteem and a lack of motivation. Previous research by the team had found that standard GP-prescribed exercise, usually gym sessions, don't work well for this group as they find them discouraging and lonely, with many dropping out very early on. The team's aim was to come up with a new type of exercise programme which would ensure that women are supported and motivated for the duration of the treatment.

The key to the new programme is 'mentored' exercise, which includes group motivational support and a low effort walking plan. Women attended sessions at their local authority leisure centre three times a week for four weeks. In each session the women received a half hour motivational coaching session conducted by a health psychologist, in a small friendly group, followed by an individually tailored exercise session on the treadmill in the gym, supervised by a sports therapist. The women exercised alongside each other, and additional emotional/social support was available to them for the duration of their session, though this was slowly decreased as confidence and the support from peers within the group increased.

Around 40 women with depression in the Nottingham area participated in the research. The new scheme was tested by comparing two groups of women; the first receiving the special programme, and the latter receiving 'exercise as usual' of the type prescribed by a GP. Women on the special programme experienced a significant improvement in their mood, physical health, sense of wellbeing, self-esteem and quality of life. They felt they had achieved these gains via a positive, comfortable and unintimidating experience which encouraged regular and continued attendance.

One volunteer said: *"I feel more confident in my physical self and my emotional self. I do think it has helped with my mood."*

In contrast, women who received an 'exercise as usual' programme experienced no significant benefits, were less likely to continue attending, and were markedly less enthusiastic. Lead investigator Professor Callaghan said: *"Exercise tailored to preferred exertion levels, combined with effective support from others, is a prescription designed to improve depressed women's overall health and well being."*

The women who participated in this study are those commonly seen in GP surgeries up and down the country. The team intend to make GPs and PCTs aware of the benefits of adding this to the range of services they make available to women living with depression through a process of educational outreach meetings in the coming months. The programme is manualised, meaning it could easily be delivered by mainstream gym staff and community mental health workers.

The research was conducted by Elizabeth Khalil, Patrick Callaghan and Ioannis Morres at the School of Nursing, Midwifery and Physiotherapy. It was funded by the Burdett Trust for Nursing, and adopted by the Mental Health Research Network, part of the National Institute for Health Research.

More information is available from Elizabeth Khalil on +44 (0)115 823 0873, Elizabeth.khalil@nottingham.ac.uk
Or the School of Nursing website, http://www.nottingham.ac.uk/nmp/research/mental-health/index.php

H. PROGRAMME PROTOCOL

EXERCISE AND WELLBEING PROGRAMME

INTRODUCTORY SESSION: UP TO 8 WOMEN

- Liz welcomes to the study explains the consent process
- Consent forms signed
- Participants asked to complete part 1 of questionnaire pack, reminds data kept anonymised – Liz circulates to assist
- Liz and Ioannis record resting blood pressure and heart rate of participants
- COFFEE BREAK
- Participants asked to complete part 2 of questionnaire pack
- Close, thank you, and reminder of first session (location, time and date, what to wear)

Approximate duration: 90 mins.

* Ask Ss to allow two hours

SESSIONS 2- 13: UP TO 8 WOMEN

- Liz and Ioannis carry out the MI and exercise protocols

Approximate duration: Exp 53-73 mins. Cont 42-62 mins.

* Ask Ss to allow one and a half hours (expect longer times with more women)

PLENARY SESSION: UP TO 8 WOMEN

- Liz thanks participants
- Participants asked to complete part 1 of questionnaire pack – Liz circulates to assist
- Liz and Ioannis record resting blood pressure and heart rate of participants
- COFFEE BREAK
- Participants asked to complete part 2 of questionnaire pack
- Participants thanked, certificates and vouchers and maintenance info. handed out
- Participants invited to stay for focus group with COFFEE BREAK

Approximate duration: 70 mins. + optional 30 mins. focus group

* Ask Ss to allow 2 hours

J. EXERCISE PROTOCOL

Experimental group

1) Recording of the resting heart
(3-5min resting on the mattress).

2) Calculation by Ioannis of the 80% safe limit of the heart rate reserve for 5-6min. Analogous regulation of participants' heart rate devices; safety sound signal when reaching the 80%.

3) 5-10min of stretching on the mattress

4) Exercise intensity at preferred levels based on the participants' personal choice. 10-40min duration subject upon the participants' desire.

Periodic heart rate recording by Ioannis.
Perceived physical exertion recording by Ioannis (participants are shown periodically the Borg's CR10 scale to rank sensations of discomfort-pain.
Social support for exercise by Ioannis during the session to ensure correct protocol application and safety (no under/overestimation).

According to clinical indications in depressed patients this methodology creates an easy and comfortable session for the participants with increased internal locus control and physical self-efficacy (Morres, 2003; Morres et al., 2005)

5) 5-10min stretching on the mattress

6) Feedback by Ioannis for 5-10min

TOTAL TIME: approx.
Minimum=35min
Maximum=80min

Control group

1) Recording of the resting heart
(3-5min resting on the mattress).

2) Calculation by Ioannis of the 50%-80% of the heart rate reserve for 5-6min. Analogous regulation of participants' heart rate devices for sound signals; training within these heart zones.

3) 5-10min of stretching on the mattress

4) Exercise prescription based on the guidelines of the British Heart Found and the American College of Sport Med (50%-80% on the heart rate reserve for 20-40 min). Gradual increases in intensity and time per session.

Periodic heart rate recording by Ioannis.
Perceived physical exertion recording by Ioannis (participants are shown periodically the Borg's CR10 scale to rank sensations of discomfort-pain.
Basic Social support for exercise by Ioannis for safety.

According to clinical indications in depressed patients this methodology creates a less easy and comfortable session with unpleasant training impact accumulation and lower levels of locus control and physical self-efficacy compared to the experimental (Morres, 2003; Morres et al., 2005)

5) 5-10min stretching on the mattress

6) Feedback by Ioannis for 5-10min

TOTAL TIME: approx. 60min ± 10min

Underlined sectors: to be confirmed by the user-steerer as to whether these sectors:
are prescribed by GPs
are offered in the exercise referral schemes

APPENDIX J. MOTIVATIONAL INTERVIEWING PROTOCOL

RATIONALE

We're aiming to maximise engagement through formalised social support in order to minimise the attrition rate for our study, and enable lasting change in the health behaviour of our participants. This group are characterised by low motivation and report feeling challenged by exercise regimes (Owen S and Khalil E 2006). The motivational interviewing approach encourages ownership of behavioural change; belief in the possibility of change, an important motivator; and hope in a range of available possibilities. MI is a counselling method specifically designed to evoke changes in health behaviour, it is client centred, and is directive (Rogers C 1951; Miller WR 1983; Miller WR and Rollnick S 1991; Rubak S, Sandboek A et al. 2005).

'The strategies of MI are more persuasive than coercive, more supportive than argumentative, and the overall goal is to increase the client's intrinsic motivation so that change arises from within rather than being superimposed from without' (Rubak S, Sandboek A et al. 2005).

In their meta-analysis Rubak et al. (2005) found that MI outperformed traditional advice giving, and was effective in group interviews and in 'one off' brief 15 minute sessions, making it an ideal choice for this study.

GENERAL APPROACH

Motivational interviewing technique will be employed to support participants in the experimental arm in engaging with the programme and gaining maximum benefit from their participation, in terms of short term gains, but also lasting strategies for maintaining this change. The Transtheoretical Stages of Change (TTM) model (Prochaska JO and DiClemente CC 1984) will be utilised as a theoretical basis, comprising:

1. Pre-contemplation

2. Contemplation

3. Preparation/Determination

4. Action

5. Maintenance

6. Relapse

It is anticipated that participants will enter the study at stage 2, 3 or possibly 4. The study aims to conclude with the majority of participants at stage 4 or 5, and the latter sessions will address how to continue at 4 or 5, and what to do in the event of 6.

GUIDING PRINCIPLES FOR THE PROTOCOL:

Participants own reasons for change in exercise behaviour will be elicited. Participants will be allowed to explore their problems with achieving physical activity and obstacles to change in a supportive safe environment. The participants will be the resource in finding solutions to their challenges.

- Participants will do the majority of the talking.
- Reflective listening will be used directively to facilitate changes in thinking and in actions.
- Ambivalence toward change will be resolved through demonstration of the discrepancy between present exercising behaviour and exercise goals.
- Arguments about change, and reasons for change arising from the programme staff as opposed to the participants are to be avoided, as will other verbal challenges to the participants such as 'WHY?' questions.
- Acceptance is vital, ambivalence is normal.

- Belief in change will be harnessed and reinforced at every opportunity.
- The 5 key self-motivational areas will be listened for and reinforced at every opportunity:-
- Concern about change
- competence to effect change
- knowledge of obstacles and devising own strategies for overcoming them
- desire to change
- self-worth
- Participants ownership of and responsibility for change is fundamental.

SESSION 1: UP TO 8 WOMEN

Liz welcomes participants to the session, celebrates attendance, reinforcing belief and hope in change.

Liz facilitates group in a general discussion, 'how do we feel about participating in this programme?', designed to establish each participant's stage of change. It is assumed that participants will fall within the contemplation or, hopefully the determination stage, some may be in the action phase already.

Eliciting phase: Liz will elicit self motivating statements from the group and reasons for change. Addresses the contemplation stage of change.

Liz to select from the 'options for sessions' listed below the most appropriate activity for the group at this stage.

Approximate duration: 15 mins.

HAND OVER TO IOANNIS

Celebration of each participant's achievement, reinforcement of belief in change and hope in change. Reflection by the group of progress made, and goals achieved.

Approximate duration: 5 mins.

SESSIONS 2-13: UP TO 8 WOMEN

Liz welcomes participants to the session, conducts introductions and celebrates attendance, reinforcing belief and hope in change.

Liz facilitates group in a general discussion, 'how do we feel about participating in this programme?', designed to establish each participant's stage of change. It is assumed that participants will fall within the contemplation or, hopefully the determination stage, some may be in the action phase already.

Liz to select from the 'options for sessions' listed below the most appropriate activity for the group at this stage.

Approximate duration: 15 mins.

HAND OVER TO IOANNIS

Celebration of each participant's achievement, reinforcement of belief in change and hope in change. Reflection by the group of progress made, and goals achieved.

Approximate duration: 5 mins.

OPTIONS FOR SESSIONS

Eliciting phase: Liz will elicit self motivating statements from the group and reasons for change. Addresses the contemplation stage of change.

Information phase: group analysis of benefits and costs of change in exercise behaviour, directed by Liz, but originating from the group. Addresses the determination stage of change.

Negotiation phase: Participants will be facilitated in devising personalised SMART exercise goals, all suggestions will be valued, resolution of ambivalence arising from the discrepancy between the current exercise behaviour and these goals will be promoted. Addresses the determination and action stages of change.

Liz will facilitate the group in determining how to identify relapse and strategies to avoid relapse. Addresses maintenance of change.

Liz will facilitate any relapsed participants in renewing the contemplation stage of change.

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