

A Lifetime's Health Delivered Creatively

An investigation of the change in patient self-reported depression amongst people with mild/moderate depression and low levels of personal social capital accessing a participatory arts course.

Research Protocol - Version 2

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ABSTRACT

Aim

The aim of this project is to examine the change in depression scores amongst people with mild to moderate depression and low social capital who participate in an arts course, and to explore the reasons behind such changes.

Rationale

The Government has taken a number of steps in recent years to improve recognition, access and care for people experiencing depression (DH, 2004). Clinical guidelines for the management of depression in primary and secondary care have been introduced (NICE, 2006) alongside a quality and outcomes framework (QOF) for GPs, which should provide a firm basis for clinical decision-making.

Despite this, actual shortages of psychological treatment following diagnosis may slow progress in dealing with new cases. In order to achieve the targets set in the National Service Framework for Mental health (DH, 2004), Layard (2005, p.3) argues that a further 10,000 therapists would be required. Given the current climate of limitations to health cost expenditure, it seems unlikely that the need for effective treatment can be met and alternative ways of meeting demand need to be explored.

A growing but largely qualitative evidence-base on participatory arts suggests that such programmes can be beneficial to individuals experiencing mental health problems through boosting their self-esteem, social participation, self-confidence and well-being and the government (ODPM, 2004) is committed to supporting the development of a this evidence base. This project is one of a number of projects that will contribute to the achievement of this aim. This exploratory mixed methods study will pave the way for rigorous evaluations using comparison or control groups.

Recent guidance on the management of depression in primary and secondary care from the National Institute for Clinical Excellence (DH, 2004) emphasised that diagnosis and treatment of depression has been based on an inadequate medical 'diagnosis' which does not take into account important social and environmental factors. This study responds to this concern, by focusing on one particular sub-group among sufferers of mild to moderate depression - individuals with low 'personal social capital' - who may be less likely to benefit from traditional forms of treatment (medication, counselling or short term CBT) in that they may not address underlying factors that may have precipitated the depression.

Definitions of personal social capital vary, but in this context it might be defined in terms of a partner with whom to confide, other close friends to confide in and enjoy time with, broader social networks from which to draw emotional and practical support, as well as engagement in social institutions that provide regular shape to and meaning in life such as work, education, religious or community groups.

In addition to potentially being less likely to benefit from traditional forms of treatment, this group in theory may also have considerable capacity to benefit from a socially oriented arts intervention such as that to be implemented in this project since the project will offer opportunities for enhanced social participation, in a supportive environment

which may boost self-esteem, perceived social support and levels of trust which in turn may promote positive mental health and buffer individuals against future vulnerability.

A structured, group-based 12-week course of arts activities for people with levels of depression suitable for treatment / care within the scope of primary care will be implemented. The course, delivered in two-hour sessions each week, will introduce individuals to a range of art forms in a community setting. It will run 10 times between 2007-2009 involving around 10-15 people per course. Two courses will be run starting in September 2007, as pilots, to enable testing out of tools and course content/schedule.

1 Research questions

The study will address the following research questions:

1. Is there a clinically relevant change in self-reported depression amongst patients accessing a participatory arts course?
2. To what extent does participation in the arts course appear to be responsible for any observed reduction in depression scores?
3. What are the costs, and estimated cost-savings and cost-benefits of the course?
4. How efficient and effective are new partnerships and referral arrangements associated with the delivery of the programme of courses?
5. How replicable is the intervention?

2 Methods

A mixed method research design, including self-completion questionnaires at baseline, post-intervention and follow-up, as well as face to face interviews with participants will be used to measure the changes in depression score, and to explore the potential reasons for such change. Focus groups with staff, recording of session activity records and use of participation rate monitoring forms will be used to assess the organisational issues in referral and delivery of the course.

To address the first research question, which aims to assess change in depression scores, self-report depression will be measured using the Hospital Anxiety and Depression Scale (HADS). A self-completion questionnaire incorporating the HADS will be completed by participants before the course (baseline), one week after completion of the course (13 weeks after baseline) and 12 weeks after completion of the course (24 weeks after baseline). Patients will not be asked to complete the questionnaire whilst attending the course or in the social context of the course.

To address the second research question, which seeks to explore reasons for observed changes in depression, a range of methods will be employed. This aspect of the study aims to build on and refine the theoretical framework that has been developed for the study. The theoretical framework sets out the potential course based mechanisms of change. The evidence to support these mechanisms will be investigated, and in addition, the framework will be extended to incorporate factors that are extraneous to the course

such as the effects of other services or treatment, or changes in personal circumstances which are unrelated to course participation.

A range of mechanism variables will be measured using a range of validated measures, which have been incorporated into the above, mentioned self-completion questionnaire, including self-esteem, personal social capital (social support, trust and participation) and well-being. From previous qualitative research these are known to be relevant client perceived benefits of participation in arts interventions, and in addition, there is a growing body of evidence to suggest that these factors may well contribute to positive mental health, prevention of depression, and resilience. Data on these outcomes will contribute to the interpretation of any observed reductions in depression scores since correlations of these variables with depression scores would provide some support for an interpretation that the course had played a part in bringing about any observed improvements in depression. Participants will also be asked to rate the value of participating in the arts course to the mental health and social outcomes in the follow up questionnaires at 13 and 24 weeks. This will allow a quantification of clients' perception of the role of the programme, which can be juxtaposed with the above data.

This research question will also be addressed by eliciting patients' perceptions of the potential factors involved in any change will also be explored in qualitative interviews with a small sample of participants at 13 and 24 weeks. The sample will be taken purposively - where participants in sampling units represent key sub-groups of interest. The interviews will explore with patients their initial mental health and social circumstances on seeking help from the GP, the sorts of changes they have or have not experienced, and the range of factors that may have contributed to such changes or lack of them (including factors intrinsic and extraneous to the course); where Time Being has played a role, this will be explored in more detail. The views of artists will also be taken into account in relation to this – and these views will be established through a focus group with the artists.

The third question, which relates to costs, cost savings and benefits will be addressed through a range of ways. Costs of delivery of the intervention and of health care prior to, during and after participation in Time Being will be identified. Patients will be asked for permission to request data from GPs regarding medication and service use. With unit costs regarding service use and costs of medication, researchers will then be able to translate service use into costs and estimate cost savings resulting from participation, with appropriate caveats regarding the attribution of causation. Cost benefits will be assessed through juxtaposing costs with changes in depression scores.

The fourth question, which seeks to examine the efficiency and effectiveness of new partnerships and referral arrangements associated with the delivery of the programme of courses will be assessed primarily through focus groups with PCMHT staff, which will explore the referral arrangements. It will also be examined by analysis of participation rate monitoring forms, which will be completed by referring staff and the local principal investigator who will enrol course participants. This data collection will enable the comparison of the profile of patients eligible to participate and who do participate, with those who are eligible but who do not choose to participate. This will enable the effect of the self-selecting nature of the sample on the representativeness of the sample of the population of people presenting with mild-moderate depression to be understood.

The fifth research question, which will examine the replicability of the course, will be examined in the focus groups. Supporting artists' accounts in these focus groups and providing evidence for analysis in their own right, session record forms will be completed by artists after each session to record the content of the class and the issues in delivery. In addition course review forms will be completed by the lead investigator after each course.

Discussion and conclusion

Overall, the study will provide a quantification of change in depression scores, and an account of the potential reasons for such change for this group. In addition it will provide an account of the delivery issues involved in new partnerships between referral and delivery teams as well as a cost-benefit/cost savings analysis. Finally it will provide an assessment of the prerequisites required for a rigorous control or randomised control trial, which will enable the evidence base to move up the staircase of medical science. Providing the case for such a trial can be made, a protocol for such a study will be developed. The details of the prerequisites are set out in the second annex in the protocol.

SECTION 1: BACKGROUND AND RATIONALE

1. General introduction

This section provides an introduction to the specific project outlined here and the programme it forms part of (i.e. Invest to Save). It also provides an overview of the literature and evidence base in relation to arts in health and depression and identifies how the proposed research aims to add to this evidence base.

2.1 The Invest to Save budget

The project described in this protocol is funded through the HM Treasury's Invest to Save Budget (ISB). ISB was created in 1998 to fund innovative projects with the potential for transforming public services but that need support in developing an evidence base of what works and what does not work before this potential can be unlocked. Projects are spread across the public sector, involving central government, local government, health authorities, police and others. A prerequisite of ISB funding is that each project must bring together two or more public bodies and/or private and voluntary sector partners to deliver services in an innovative fashion. It supports projects at various stages of development including pilot projects testing out new ideas with a view to their being incorporated into mainstream service provision if cost-effective. Evaluation of the cost-effectiveness of innovations is a fundamental part of all ISB projects, and essential if organisations and agencies both locally and in other parts of the country are to consider adopting the service model.

This project is one of three that constitute a programme - 'A Lifetime's Health Delivered Creatively' - funded through the ISB. The programme, which is led by the Healing Arts team within the Isle of Wight NHS Primary Care Trust, was awarded a total of £850,000 in 2006 from the budget. It is sponsored by the Department for Culture Media and Sport (DCMS) and the Government Office for the South East. A programme of arts courses is being developed and implemented with three different populations working within and alongside mainstream healthcare on the Isle of Wight. The programme will take place over three years - over which period this study will investigate the potential health and economic impacts with a view to identifying the potential for financial savings arising from each project. The three populations are stroke survivors, overweight or obese children, and adults with mild to moderate depression.

2.2 Overview and rationale for the project

The project will establish a time limited participatory arts course for people with mild to moderate depression and low 'personal social capital'¹. The course will be targeted at depression, since there are relatively high rates of depression and suicide on the Isle of Wight compared with other parts of the South East region (Nurse & Campion, 2006), and

¹ Definitions of personal social capital vary, but in this context it might be defined in terms of a partner with whom to confide, other close friends to confide in and enjoy time with, broader social networks from which to draw emotional and practical support, as well as engagement in social institutions that provide regular shape to and meaning in life such as work, education, religious or community groups.

the due to the relatively limited resources available for mental health services in primary care.

The decision to focus on those with low personal social capital responds to the concerns expressed in recent clinical guidelines for management of depression in primary and secondary care (NICE, 2004) that diagnosis and treatment of depression is unhelpfully based on a limited 'diagnosis' which does not take into account important social and environmental factors:

“[Depression]... is too broad and heterogeneous a category, and has limited validity as a basis for effective treatment plans. A focus on symptoms alone is not sufficient because a wide range of biological, psychological and social factors have a significant impact on response to treatment and are not captured by the current diagnostic systems.”

The focus on people with low personal social capital also responds to the body of evidence (see Section 3) which demonstrates both that those with low personal social capital are particularly vulnerable to negative life events which are commonly associated with the onset of depression and also that projects delivering social support (as a substitute for personal social capital) may promote recovery and further deterioration of symptoms.

There is a clear rationale for a course that may offer benefits through a social means, such as a group-based participatory arts course. Participation in the arts has the potential to benefit most people, since it offers meaningful, enjoyable forms of self-expression in a sociable context. It may be particularly valuable, in health terms for those with low personal social capital since it offers a naturalistic and relatively simple way of making friends. Since it allows reciprocal social relations to emerge naturally, it may be more effective than other forms of social support such as volunteer befriending where the nature of the relationship is one-way. Similarly its focus on enjoyment and creativity rather than personal problems may have advantages over support groups where support may be problem-focused. The course to be implemented will introduce people to a range of art forms, and it is intended that in addition to the immediate benefits participation may bring, that participation in the arts may be sustained after the course, and become a part of participants' lives providing a source of resilience. Section 3 sets out a theoretical framework that underpins the design of the course and research.

2.3 Policy relevance

The study relates to standard two of the National Service Framework (NSF, 1999). Standard two aims to improve access to primary care and other services for people experiencing mental distress. Craig and Boardman (1997) contend that for most people (around three quarters), the distressing symptoms of life events commonly associated with mild depression are resolved without need for medication or psychological treatment within a year. However they state “that around 20% are still symptomatic after three years”. We believe that the people who are the subject of this proposal (those with low social capital) are more likely to be amongst this latter type.

A number of steps have been taken to improve care access for people experiencing depression. The introduction of clinical guidelines for the management of depression in

primary and secondary care (NICE, 2006) provides a firm basis for clinical decision-making. The incorporation into the GP quality and outcomes framework (QOF) of the requirement to use validated tools to measure the depression of their patients may result in better recognition of depression in primary care, since the QOF is linked to the GP payment system.

According to Layard (2005) the lack of psychological treatment available following diagnosis may slow the pace of progress on standard two and a further 10,000 new therapists are required in order to improve upon the current treatment of those with depression for whom “*there is usually little help other than a few minutes with the GP and some pills*” (Layard, 2005, p3).

In the current climate of health cost limitation, it seems unlikely that Layard’s call for this volume of therapists will be met, and alternative ways of addressing depression in primary care such as arts courses which build self-esteem, and personal social capital may become important as a way of avoiding the need for more costly interventions or treatment. This is not to say that participatory arts should be set up as an alternative for psychological treatment, rather as a means of preventing mild to moderate needs develop to the extent that psychological treatment is deemed necessary. Thus a particular concern of this project is to identify whether the course to be implemented, through its ability to unleash creativity, provide opportunities for participation in enjoyable activities, and through its socially reintegrative mechanisms, can reduce the need amongst those participating, for more costly psychological treatment. By focusing on those with the least social support and resources available to them to address their depression, the course may make a contribution.

The study also relates to standard one of the National Service Framework (NSF) for Mental Health (DH, 1999) which concerns promotion of mental health and well-being amongst groups at particular risk of poor mental health. The health promotion agenda encompasses action in communities, schools, workplaces and neighbourhoods to support mental health. The Sainsbury Centre has described mental health promotion as “*any action to enhance the mental well-being of individuals, families, organizations and communities*” (Sainsbury Centre, 2004). In working towards standard one, agencies are encouraged to develop services to strengthen individuals, communities and reduce barriers to mental health. Strengthening individuals involves “*increasing emotional resilience through interventions designed to promote self-esteem and develop life skills*” whilst strengthening communities involves “*increasing social support, social inclusion and participation*”.

The outcome of health promotion is ‘well-being’ which brings together concepts from mental health and quality of life. The concept embraces both prevention of mental distress. In addition through the social model of mental health, which emphasises social factors involved in well-being, it is believed that ‘well-being;’ is achievable even amongst those experiencing mental distress. It is contended that well-being can exist independently of sustained difficulties such as disability and mental ill health, in the same way that people with physical impairments can be disabled or enabled by the society they live in. Considerable work has been undertaken to develop and validate measures of ‘well-being’ that would help to indicate the extent to which communities had succeeded in meeting standard one. We have incorporated one of these tools into the set of

questionnaires that intend to use to evaluate the success of the course to be implemented as part of this project.

Underpinning the NSF as well as being a policy aim in its own right, is the social inclusion agenda. Social inclusion involves addressing factors that exclude key groups in society. Social exclusion is a term used to describe the process or result of a person's being shut out from the social, economic, political and cultural systems that constitute normal community participation². Recent work by the National Social Inclusion Research Coalition identifies three strands to social inclusion in the arena of mental health which incorporate access to user-centred mental health services, access to a standard of living which offers "*a fair share of the benefits of modern society*" and social participation that offers "*diverse roles, relationships and connections*" (Secker, 2007).

This latter strand of social inclusion - which relates to social participation – is important to the proposed study, in keeping with the proposed role envisioned for the arts in mental health proposed by the Social Exclusion Unit:

"Arts are believed to have a therapeutic role as well as helping people reintegrate into wider society by increasing self-esteem, confidence and social networks. In one survey, roughly half of participants reported feeling better or healthier since becoming involved in the arts."
(ODPM, 2004, p83)

Work is underway under the auspices of the National Social Inclusion Research Coalition to develop and validated measures of social inclusion, however this work is progressing at a slower pace than work to measure 'well-being' under the health promotion agenda. Tools are beginning to emerge and where available will be used for this project.

Whilst the potential contribution of the arts to mental health policy objectives has been identified, there is currently little rigorous evidence. The need to establish the evidence base is noted frequently in the literature on arts in health since 2000 (White, 2003; CAHHM, 2003, Geddes, 2003; Hacking et al, 2006; IPPR, 2003, Jermyn, 2001), and action to do so was one of the 27 action points set out in the Social Exclusion report (ODPM, 2004):

"The Department for Culture, Media and Sport (DCMS) in partnership with the Department of Health (DH) will give priority to undertaking research to establish the health benefits and social outcomes of participation in arts projects and the characteristics of effective local projects."
(ODPM, 2004, p106)

3 Arts and health

'Arts in Health' forms a field of practice where the arts sector and the health sector coincide. As a field it has several distinct areas of practice for example: arts in the

² There is not scope to provide a discussion of the concept of social exclusion, its causes, and consequences for mental health here, however, readers might wish to see ODPM (2004) Jermyn (2001) and Secker (2007) for further information – the latter two provide good reviews of the literature pertaining to social exclusion, mental health and the arts.

healthcare environment (e.g. design of ‘healing’ environments, and the use of performing or visual arts in GP wait rooms and hospital wards); community arts (e.g. health promotion through the use of arts); medical humanities (e.g. arts as part of practising medicine); and arts therapy (e.g. working directly, and diagnostically with patients through art)³.

The arts course to be implemented during this project can be described as ‘participatory arts’. As a form of practice participatory arts emanate from the social model of health, emphasising the social and environmental factors involved in individual health differences. Those focused on mental health aim to promote positive mental health outcomes through active participation in the arts, without explicit reference to mental health problems. Delivered by artists, they offer individuals with or at risk of poor mental health the opportunity to join in enjoyable group-based arts activities in an informal, non-medical environment. They aim to nurture individuals’ artistic abilities in a creative and supportive environment, as well as nurturing individuals’ self-esteem and social participation. They are not intended to replace appropriate proven techniques for the treatment of specific mental problems but it is believed that they can provide a contribution to the overall mental health and well-being of people experiencing mental health problems. Thus patients accessing participatory arts may well be in receipt of psychological or medical treatment alongside.

Participatory arts are distinctly different from arts therapy, which is conceptually located within the medical model of health, assisting diagnosis and treatment. Arts therapy tends to be used to support communication and forms a part of individual therapy with people with more substantial needs such as, for example, people with schizophrenia, dementia or people who have experienced a disabling stroke. It tends to involve both mental health and arts practitioners trained specifically in arts therapy, and will take place in a medical environment as a feature of treatment.

Participatory arts broadly fall within two camps: ‘community arts’ and ‘arts on prescription’. The former tend to be open-ended programmes for community members in order to promote personal social capital and the health and well-being of the individual community members (see Everitt & Hamilton 2003), examples of which might include the *Arts for Recovery in the Community* project in Stockport and *St Luke’s Art Project* in Manchester. Projects may receive funding from local authorities and grants from charitable organisations, and are ‘open to the community.’ They tend not to focus on specific mental health needs, preferring an ‘open-access’ approach in keeping with an underpinning philosophy of inclusion, equality, and user-led service delivery.

Arts on prescription projects on the other hand, have emerged in response to a call for their development in 1998 by the then Chief Medical Officer Sir Kenneth Calman (see Butler, 2001). They are based on other GP referral schemes such as exercise referral scheme whereby GPs identify patients who would benefit from such schemes and offer to refer them to time limited arts projects. Compared to community arts, they may be more directive and service-led. They have often been set up in conjunction with, and seen as a key partner in the provision health and social services. *Stockport Arts on Prescription*

³ For more information see the National Network for Arts in Health (<http://www.nnah.org.uk/>)

scheme⁴ – evaluated by Huxley et al (1997) is an example of this latter type, as is the arts course to be implemented as part of the present project.

Most of the evidence on participatory arts in mental health is qualitative - there have been few quantitative studies. Overwhelmingly the qualitative evidence suggests that the benefits of participatory arts programmes are in the areas of self-esteem, social participation, self-confidence and well-being of those participating.

A number of studies have been funded by the Government, which will contribute to filling the gap in evidence on the effects of arts projects on mental and social outcomes. Anglia University was commissioned in 2004 to develop an evaluation framework and appropriate indicators of mental health and social inclusion outcomes for use by participatory arts projects. The work identified that three outcome areas were relevant to participatory arts including mental health status, and social inclusion and ‘distance travelled’ towards each of these (Secker 2005).

The forthcoming report, which sets out the evaluation framework, provides a self-completion questionnaire for use by participatory arts projects seeking to measure their success. The questionnaire incorporates a global mental health rating measure, and questions to measure the use of primary and secondary care services and medication. It incorporates a new social inclusion measure, which measures social contact, client perceived stigma and discrimination, engagement in employment and education and neighbourhood cohesion. Finally, ‘distance travelled’ towards mental health and social inclusion is measured using a modified version of an existing measure of ‘user empowerment’ (Secker, 2007). Some of the content of this self-completion questionnaire has been used in the design of this study. However many of the questions and measures used in the present study have been specifically selected to respond to the research questions that this study will address, and to fit the group that is the subject of this study.

Two studies of ‘arts-on-prescription’ projects have been funded through the Treasury’s *Invest to Save Budget*. The first based in Sefton aims to benefit people suffering from stress and depression, as an alternative to the prescribed tranquiliser benzodiazepine or to aid withdrawal for those who have been long-term users. The second is the arts course described in this protocol for people with depression and low social capital.

4 Context for delivery of the programme of arts courses

4.1 Local context

The Isle of Wight is a relatively deprived area of the South East. Most of the electoral wards of the Island are in the second most deprived quartile of the Indices of Multiple Deprivation (IMD), and four are in the most deprived quartile i.e. the most deprived 25 percent in England. There is also a higher prevalence of mental ill health on the Island compared with the rest of the South East. The South East Public Health Observatory (SEPHO) reported that many of the socio-economically deprived areas coincide with areas of high mental ill health (Nurse & Campion, 2006). For 2004, most of the wards in

⁴ For more information about these projects see <http://www.wlct.org/gmahn/casestudies.htm>

the Isle of Wight were in the worst quintile of all South East wards on a combined indicator for mental health. The combined score incorporates the following indicators:

- Proportion of the population committing suicide in a year⁵;
- Proportion of the working age population claiming benefits for depression or anxiety;
- Proportion of the population receiving drug therapies for depression or anxiety;
- Admissions to hospital for depression or anxiety, for wards in the South East⁶.

Notably, despite the high needs, the 2006 SEPHO Health profile for the Isle of Wight for 2006 reports that mental health treatment and provision is significantly better in the Isle of Wight than in England, and further that NHS performance rating for 2005 for the Isle of Wight Mental Health Trust gave it a rating 2 (indicating a good performance overall). The programme of courses will be delivered in Newport, which is north of the centre of the Isle of Wight. Holding the course in this central location was favoured since it is relatively easy to get to from most parts of the Island, and since it is a hub for cultural events on the Island. Whilst there are other venues on the Island, it was hoped that by attracting participants to Newport they could be linked into the large number of existing classes, courses and events that take place in Quay Arts Centre's arts workshop based at Jubilee Stores in Newport. There are some concerns that despite its relative proximity residents of some of the more deprived wards are unlikely to travel to Newport. Travel costs will be refunded to those who need to claim them.

4.2 Source of referral and recruitment

The arts course will be provided within primary care. The Healing Arts Team, which will deliver the course, has established links with primary care, and the focus on patients with mild to moderate mental health problems means that the course may be delivered by artists, without need for attendance by a mental health practitioner.

The course will recruit participants from amongst patients accessing the Primary Care Mental Health Team. The Primary Care Mental Health Team (PCMHT) is a resource for people with mild to moderate mental health needs, providing assessment, information, signposting, workshops and support for patients with common mental health needs such as depression, stress, anxiety, poor self-esteem, difficulties with assertion, mild eating disorders. Patients are given information about the support the team can provide by GPs. Patients access the team themselves rather than being referred by their GP. The role of the team in this project will be to identify patients who meet the inclusion criteria, and who do not meet the exclusion criteria and to provide them with information about the arts course. Patients interested in participating will then contact the arts team.

Patients who require secondary care such as the services of the Community Mental Health Team, assertive outreach team, early intervention team or inpatient care would not be eligible to access the course since their needs have already progressed to substantial or critical, and would therefore be beyond the scope of the course.

⁵ Within the South East region, the Isle of Wight, Brighton and Hove and Eastbourne had the highest rates between 2001-2002, with between 13-16 people per 100,000 in the Isle of Wight committing suicide.

⁶ The rate for the South East is 8.39 and for England 8.65. The Isle of Wight also has the highest rate of hospital admissions for mental illness.

5 Project delivery

The arts team, employed by the Healing Arts department of Isle of Wight NHS Primary Care Trust, has led on the design of the course and the team will deliver the course in Quay Arts, Newport. Guy Eades (Director, Healing Arts and Chief Investigator) and Jacqui Ager (Local Principal Investigator) have led with the development and establishment of the project. Ms Ager is also responsible for induction of clients onto the programme (described later). The team of artists who will deliver the course have experience of working with people with mental health problems. The team includes:

- Colin Riches – lead artist;
- Liz Bolwell – movement specialist;
- Lucy Wells – visual artist, carnival, working on drawing ahead;
- Carol Jaye – creative writing, ceramicist;
- Maggie O'Connor – musician.

As noted above, the PCMHT will be the principal source of clients for the course. In addition to the team manager, David Sellers, there are five PCMHT staff that provide support to patients across the island. Each member of staff covers one or more 17 GP practices on the Island. Team members are all qualified mental health practitioners.

Matrix Knowledge Group, a London based research and evaluation company have led on the design of the evaluation and will continue to be involved in management and delivery of the research, analysis and reporting. Key members of the team include:

- Andy Beale (Head of Health research and Consultancy, Matrix) – Project Director;
- Elaine Stewart (Managing Consultant, Matrix) – Project manager;
- Matt Baumann (Freelance Researcher with Matrix) – Operational research lead for Matrix;

A project committee is overseeing the progress of the project and will report to the sponsors of the research. The committee consists of Matt Baumann (for Matrix Knowledge Group), Guy Eades (Healing Arts, Isle of Wight NHS PCT), and Tara Dean (Research and Development Support Unit, Isle of Wight NHS PCT).

More details of the roles and responsibilities of these stakeholders can be found in Section 6.

SECTION 2: THE DESIGN AND DELIVERY OF *TIME BEING*

6 Background

The participatory arts course to be implemented and evaluated as part of this project is called Time Being. The design and content of the proposed course has drawn inspiration from a course developed in 2002 for people with mild to moderate mental health problems, which was implemented as part of the Isle of Wight's Healthy Living Programme. The course ran ten times between January 2003 and March 2005 and involved one hundred participants, with referrals to the programme coming from GPs, the Primary Care Mental Health Team, and through self-referral.

7 Aims and objectives

The overarching aims of the course proposed here are to contribute to:

- Sustained reductions in the degree of depression and anxiety reported by participants; and
- Sustained reduction in participants' use of antidepressants and primary and secondary mental health care.

To fulfil these aims there are several objectives:

During the course

- To provide an environment in which participants can make new friends;
- To introduce participants to a range of enjoyable arts activities; and
- To contribute to improvements in participants' self-esteem and 'well-being';

Beyond the course

- To give participants sufficient interest and confidence to continue to be involved in arts activities after the course has finished enabling ongoing self-expression and social participation;
- Through improved self-esteem and new social bonds to enable participants to feel more confident in their ability to make and sustain enjoyable, supportive and reciprocal social relations;
- To contribute to an increase in participants' desire/ability to participate in further education, training and work.

8 Details of the schedule for delivery of the courses

Time Being will run up to 10 times, between January 2008-December 2009 with between 6-15 people accessing each course. In addition, the course will be piloted through two runs of the course starting in September 2007 (see Table 1 below for details of the schedule of courses). During this pilot all forms, information sheets, and instruments (questionnaires) will be piloted to allow for any final refinements to the course or the research.

Table 1: Schedule of courses

	Sep – Nov 2007	Apr – Jun 2008	Sep – Nov 2008	Jan – Mar 2009	Apr– Jun 2009	Sept – December 2009
Monday afternoon =>	Pilot 1	Course 01	Course 03	Course 05	Course 07	Course 09
Monday evening =>	Pilot 2	Course 02	Course 04	Course 06	Course 08	Course 10

Further information about the planned progress of the project overall can be found in Annex 1.

9 Details of course location and content

Time Being will be delivered in an informal and supportive environment in Jubilee Stores, which is linked to Quay Arts Centre in Newport. Using existing community arts settings will serve to link people into places where opportunities for further participation can easily be identified.

It is a structured 12-week course of arts activities for people with levels of depression which are suitable for treatment and care within the scope of primary care. Participants of Time Being will engage in a range of creative activities for two hours each week. They will spend two to three sessions doing each of four art forms; including visual arts, music, movement, and creative writing. There will be some overlap between art forms to enhance continuity. Activities will incorporate individual and group based work within the group context.

There will be no focus on mental health issues during the course. A key feature of participatory arts programmes - and more broadly interventions that aim to support social inclusion - is their specific concern to concentrate on health promotion rather than focus on problems. Health promotion emphasises strengths and achievements, enjoyment and participation rather than problems, diagnosis and treatment. Thus benefits are expected to result from enjoyment, and self-expression (discussed further in Section 3) rather than through any explicit focus on mental health problems.

The design of Time Being has been informed by participant feedback on previous courses and in addition, a group of mental health participants of a similar arts course were also consulted in 2006 on a range of course and research design issues. Participant feedback has informed decisions regarding the sequence of activities (described in Table 2), the content of the activities, the extent of individual versus group based activity, the level of challenge involved in the activities, as well participants' preferred style of delivery. It has also informed the design and content of the questionnaire – in particular the language used, the selection of measures, and the overall length of the questionnaire.

Course design has also been informed by a review of the literature and by the recommendations of a report on an evaluation of previous arts courses for people with mental health problems on the Isle of Wight (Secker et al; 2006). A key theme in the

literature and in the evaluation was that benefits beyond the course might be achieved if there was greater attention to this aspect in the design of the course. There has been detailed consideration and planning to address this issue (see content of final session for example).

Each course will follow the same pre-specified format that introduces participants to different art forms each week (see Table 2 below and Annex 1).

Table 2: Time Being course content

Week	Further details
Week 1 Welcoming	The first week of the 12 week course is attended by all artists involved in delivering it so that participants can meet the artists – this session will also be used to introduce the course content and to discuss the way the course runs. One or two participants from previous courses are also invited to attend the first week to talk to the group about their experiences of participation.
Week 2-3 Visual art	Visual arts include drawing, painting, sculpture, and 3D craft. It is helpful to begin the course with visual art since people may feel anxious at the beginning of the course and visual arts can be perceived as relatively ‘low risk’ activities to patients, whose participation begins with gentle individual practice, leading to more collaborative activity as the course progresses. In the final session of this art form, information about local opportunities for further involvement in visual art will be provided and discussed.
Week 4-6 Music	Music work involves percussion, voice work, song / choral activities, and listening to music. Initial anxiety about being ‘expected to sing’ is dissipated through introducing the group to interesting and unfamiliar instruments and sounds. When singing is introduced tension has been released in this earlier work and singing can feel quite natural to participants. In the final session of this activity form, information about local opportunities for further involvement in music will be provided and discussed.
Week 7-9 Movement	This involves individual and group based activity and can incorporate rhythm and song. Gentle introduction to movement can be seen as important since expression through movement is difficult and participants may feel exposed. In the view of the arts team however, this may be one of the most empowering activities of the four with participants discovering how to feel comfortable with their bodies. In the final session of this activity form, information about local opportunities for further involvement in movement will be provided and discussed.
Week 10-11 The written word	These sessions involve being read to, writing poetry and prose, and reading aloud. Creative writing is undertaken at this stage when members of the group have had a chance to enjoy the company of each other and the activities and are able to begin to use the stimulus of their enjoyment to provide a source of material to write about. In the final session of this activity form, information about local opportunities to be involved in creative writing will be provided and discussed.
Week 12 Feedback and follow on	Sustaining social benefits of participation, and building upon the ideas and opportunities participants have been introduced to is important in achieving long lasting benefits. The final week’s session will focus on opportunities for continued participation in the arts, and there will be an opportunity to consider how the group may stay in touch. There will be an opportunity for participants to discuss their interests, plans and concerns about the future individually with the artists, as well as in a group. Information about local courses will be provided and artists running local courses will be invited to attend and offer information. This final week will also be used to request feedback from the participants on the design and implementation of the course in order to attend to any particular issues.

10 Staffing

The staff delivering the arts course are artists. All have experience of working with people with mental health conditions in previous work in, for example, prisons, local mental health inpatient settings, and mental health day centres. Each artist will have access to supportive line management (and additionally regular group sessions with a counsellor) where any issues arising can be discussed confidentially. It is anticipated that each artist will lead two to three of the 12 sessions. A mid-course staff review meeting will take place at week 6 and a final course review meeting will take place at week 13.

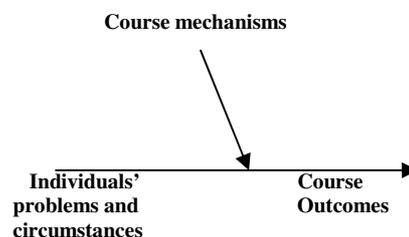
SECTION 3: THEORETICAL FRAMEWORK

Baum (2000) argues that ‘health outcomes can only be predicted by complex interactive models of causality’. In addition recent reviews of studies aiming to improve mental health through social mechanisms have argued that not enough attention has been paid in evaluations to the identification of the characteristics of individuals who benefit or who do not benefit from such interventions (Kawachi & Berkman 2000; Cohen et al, 2000). The theoretical framework developed here is an initial outline of such a model, which will be revised and amended during the research and analysis phase of the investigation, which takes account of both the potential mechanisms at work and as proposed by Kawachi and Berkman, emphasises differences between sub-groups of individual participants.

The theoretical framework is built around the concepts of individuals’ problems and circumstances, potential course mechanisms and course outcomes as a means of understanding how change occurs in individuals. ‘Individuals’ problems and circumstances’ refers to the psychological, socio-demographic characteristics of individuals participating in the course that are believed to be pertinent to the success or other of the course. ‘Course mechanisms’ refers to the ways in which the course is theorised to have an effect. ‘Course outcomes’ refers to the overall changes that might occur within individuals who participate in the course in the short, medium and long term.

The basic relationship between these concepts is illustrated below in Figure 1.

Figure 1: Concepts in the theoretical framework



This section of the protocol provides a detailed discussion of these concepts as it pertains to the evaluation and proposes an initial theory of change.

11 Individuals’ problems and circumstances

As noted previously all of the people accessing the course will have been initially referred to the PCMHT for mild-moderate depression, and will have been invited to consider participating in the course by the PCMHT if they have ‘personal social capital’ deficits (defined below). We consider below the factors in depression and the role that social capital plays in order to identify some of the key issues to be examined in the research.

11.1 Depression

Depression is characterised by a depressed mood, or loss of pleasure in everyday activities. The classification used in the National Institute for Clinical Excellence (NICE, 2006) clinical guidance on management of depression in primary care originates from the

World Health Organisation's (WHO) International Classification of Disease (ICD-10), which incorporates ten symptoms present in a major depressive episode:

- Depressed mood;
- Loss of interest and enjoyment;
- Reduced energy leading to increased fatigability and diminished activity;
- Reduced concentration and attention;
- Reduced self-esteem and self-confidence;
- Ideas of guilt and unworthiness (even in a mild type of episode);
- Bleak and pessimistic views of the future;
- Ideas or acts of self-harm or suicide;
- Disturbed sleep;
- Diminished appetite.

Mild depression is characterised by the presence of four of the above symptoms for at least 2 weeks whilst moderate depression is characterised by the presence of six of the above symptoms for at least 2 weeks, and where a considerable impact on the functional ability of the individual is observed (NICE, 2004).

Biological factors play a part in major disorders including major depression (endogenous depression), but overwhelmingly, social factors play the most significant role in explanations for depression (exogenous depression). Negative life events and in particular those that increase stress (Billings et al, 1983) and reduce social support (Lewinsohn et al, 1988) are commonly associated with depression (Dohrenwend et al, 1986). Indeed a classic community study of depression found that "*in the absence of a life event, depression was very rare*" (Brown and Harris, 1978).

There is also evidence to support a link between life events in childhood and adult depression. Poor quality care following parental death during childhood (Harris et al, 1986; Harris et al 1999), violence, parental divorce (Kessler & Magee, 1993), physical and sexual abuse (Andrews et al, 1990) and poor quality child-parent relationships and bonding (Cole & McPearson, 1993; Crook et al, 1981) are significant predictors of future depression. Halpern (2006) contends that it is the low self-esteem that results from such childhood events which lowers individuals' resilience in the face of adverse life events or circumstances.

11.2 Personal social capital

Definitions of personal social capital vary, but in this context it might be defined in terms of a partner with whom to confide, other close friends to confide in and enjoy time with, broader social networks from which to draw emotional and practical support, as well as engagement in social institutions that provide regular shape to and meaning in life such as work, education, religious or community groups.

Studies have regularly found that individuals with low levels of personal social capital are more likely to have higher rates of psychological stress and behavioural problems (Australian Bureau of Statistics, 2003), higher anxiety levels (Twenge, 2000), and a greater chance of developing depression (Brown and Harris, 1978) and higher rates of mortality (Seeman 2000, Berkman & Glass 2000).

Sociologists offer two models for the role of social capital and mental distress; the ‘stress-buffering’ and the ‘main effect’ model (Kawachi & Berkman, 2000). In the stress buffering model, it is proposed that confiding close relationships, supportive relationships and high degree of social participation buffer individuals from the effects of stressful life events or life events in which social capital is depleted (such as the loss of a partner, loss of a job, or loss of a close friend). Social networks provide emotional support and companionship. Those with high levels of social capital are protected in the face of adversity (Berkman & Glass, 2000). In the main effect model, social capital has a ‘main effect’ in which enjoyment of friends and meaningful relationships and a variety of forms of social participation promote good mental health, which supports individuals’ resilience.

11.3 Sub-groups of interest in this study

All of the participants on the course will have lower levels of personal social capital although the nature of their social capital ‘deficit’ will vary. Participants will also vary with respect to the factors have led to their depression. Most are expected to have experienced a negative life event within the previous 12 months, others may in addition have struggled with depression in the past due perhaps to childhood experiences or for biological reasons. Some may also have a personal history of depression or may be related to someone with a history of depression. Understanding how these factors might affect individuals potential to benefit from participation in the arts course will be an important feature of the study. We summarise the sub-groups that are of interest in Table 3 below and note the additional sub-groups that we will explore in Table 4.

Those who have had significant life events in childhood (or more serious recent life events) may find the benefits of participation harder to accumulate and sustain, as might those who have a family history of depression, or long-standing psychological complexities. Whilst we will be able to explore most of these factors, we will not be able to explore the impact of life events in childhood in this study, due to difficulties associated with reliable recall and the potential distress that this trying to unearth events from early life might cause.

Table 3: Main sub-groups of interest

Topic	Sub-grouping	
Social capital deficit	Social support (close confiding, family, friends)	Wider social participation
Recent life event in last 12 months	Yes	No
History of depression (may indicate biological or childhood experiences)	Previous history of depression	No previous experience
Family history of depression (indicates biological)	No close family members experience	One or more close family members

Table 4: Additional sub-groups to explore

Topic		Sub-grouping
<i>Symptoms 1</i>	Mild depression	Moderate depression
<i>Symptoms 2</i>	Depression only	Depression and anxiety
<i>Medication</i>	Medication	No medication
<i>Living situation</i>	Live alone	Live with others
<i>Sex</i>	Men	Women
<i>Age</i>	Younger	Older

12 Outcomes

In addition to offering participants the opportunity to enjoy participating in a range of art-based activities in a supportive and comfortable environment, it is intended that the course will contribute to a range of benefits to participants both during and beyond the course.

The tables below set out the main anticipated outcomes with a brief description of the rationale.

Table 5: Anticipated outcomes during and beyond the course

Anticipated outcome	Rationale
During and beyond the course	
Improvements in participants' self-esteem	This is the most widely reported benefit of arts courses amongst people with mental health, and it is contended that benefits to self-esteem are indicative of 'distance travelled' towards improved mental health ⁷ .
Reduced symptoms of depression	Reduce symptoms of depression would indicate that the course might have helped to resolve the presenting problem.
Improved personal social capital (social trust, social support and social participation).	Personal social capital is believed to benefit mental well-being and to be a factor in depression through buffering stress and through a main effect. If improvements to social capital can be made and sustained amongst people with low social capital, individuals may be protected from further deteriorating symptoms, may recover more rapidly, and be protected from future episodes. For this group, improved social capital may also be indicative of 'distance travelled' towards improved mental health
Improved mental 'well-being'.	As noted earlier, health promotion is a key theme in the NSF. The concept embraces both prevention of mental distress through well-being promotion, but also, through the social model of mental health well-being is believed to be achievable even amongst those experiencing mental distress, in the same way that people with physical impairments can be disabled or enabled as a result of the nature of the society they live in.

⁷ The role of self-esteem in mental health is fundamental: "*The most basic task for one's mental and emotional and social health, which begins in infancy and continues until one dies, is the construction of his/her positive self-esteem.*" (Macdonald, 1994, p. 19, quoted in Heenan, D, 2006).

Table 6: Anticipated outcomes beyond the course

Anticipated outcome	Rationale
Beyond the course	
Sustained reductions in symptoms of depression;	To reduce symptoms of depression and for them to be sustained would indicate that the course might have helped to resolve the presenting problem.
Sustained reductions in participants' use of antidepressants and mental health services in primary;	To reduce the need for patients to access services is key to the cost-benefit analysis.
Prevention of symptoms deteriorating, including preventing the need to access to secondary care;	To prevent needs from escalating to more serious levels.
Continued participation in arts or other socially beneficial activities;	Continued participation in arts or other activities may be an indication of 'distance travelled' towards improved overall personal social capital, based on the Kawachi and Berkman model described earlier. Continued participation offers more chance of accumulating sources of social support.
An increase in participants' desire / ability to participate in further education, training and work.	To have an impact on individuals' desire, ability and confidence to work would be a beneficial outcome in itself, but also contributes to the cost-benefit analysis.

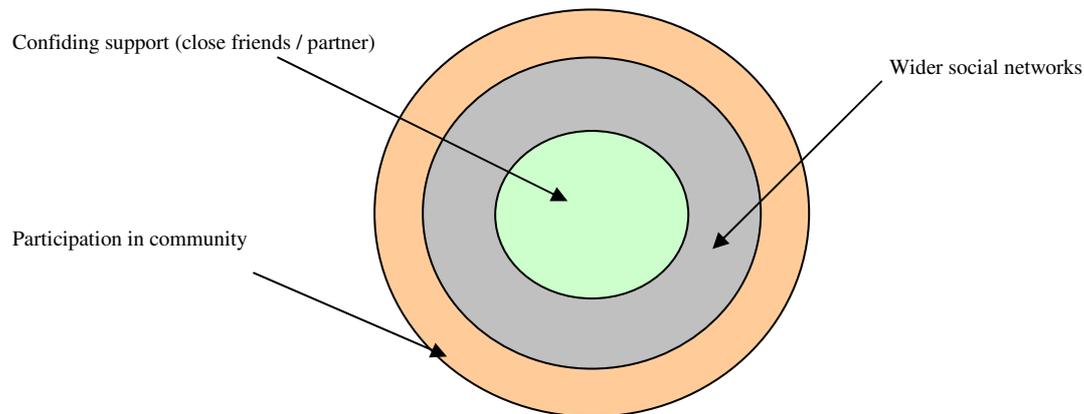
The measures that will be used in relation to each of these outcome areas are defined in the section 5.

13 Mechanisms

13.1 Short to medium term

Kawachi and Berkman (2000) propose that each of the forms of social capital (confiding relationships, social networks, and social/civic participation) plays a different role. Greater social participation they argue leads to more opportunities for social networks and close friendships to emerge, which in turn offer more potential for confiding relationships. This is illustrated below, in which the outer layers provide the context within which other levels can operate.

Figure 2: Layers of personal social capital



A course such as Time Being can provide an opportunity for individuals with low levels of personal social capital at all levels to a) participate in a community activity, and b) have the opportunity to develop wider social networks and c) perhaps to make close friends or intimate relations.

Social participation and social bonding is key to the course and both are facilitated in a number of ways. The culture of the course is one of acceptance and inclusion; participants are supported to work together on certain activities, which are designed to be 'fun'. The regular attendance at the group can facilitate the development of social bonds between group members. In particular for people going through a difficult time, or feeling alone with their problems, it offers them an opportunity to be around other people with difficulties and may help them to feel that they are not alone. The enjoyment that results from being with others in such circumstances, can allow participants to 'let go' of preoccupations with negative personal issues or anxieties, at least temporarily, through the recognition that they are not alone with them.

For those who have particular difficulties with meeting people and making friends due to low self-esteem, the safe social space allows participants to socialise, something which may, in the context of the life of the participant, or in other social contexts, be perceived by participants to be either too difficult, or prohibitively risky. Experience of acceptance, being 'welcome', and gaining new friendships supports the development of a more positive self-concept, a greater trust in others, and may reduce anxiety about being in social situations.

Overall increased personal social capital can lead to reductions in symptoms of depression through providing sources of release, confiding support and reciprocation, as well as boosting self-esteem (stress buffering). Reductions in symptoms of depression and enhanced overall 'well-being' may result from a main effect mechanism, which emphasises enjoyment of friends and participation and a sense of belonging.

This increased personal social capital explanation may be helpful, but additionally, there may be other art-based health promotion mechanisms at work which provide relief from pre-occupation or anxiety, enhance identity through achievement, self-expression and new found interests. These benefits may in turn support good self-esteem, and a sense of hopefulness.

The course introduces participants to a range of arts activities in an environment where each individual's creativity is valued and respected. The activities are, above all, intended to be enjoyable and stimulate interest and absorption. The concentration and absorption in the arts activities is thought to provide a respite from preoccupation with negative personal issues or anxieties. Participation in the activities offers individuals the opportunity to explore their creativity, to express this through the use of a variety of different art forms, and to trust and value their responses to such creative activity. Participants may discover or rediscover interests or creative skills, and may experience pride and satisfaction from the completion of a piece of artwork.

These various 'journeys' of self-expression and growing self-efficacy may be enjoyable as well as challenging. Discovery of an art form that is meaningful to the participant and provides a sense of purpose and may contribute to a clearer understanding of one's likes and dislikes, a stronger sense of self and enhanced self-esteem.

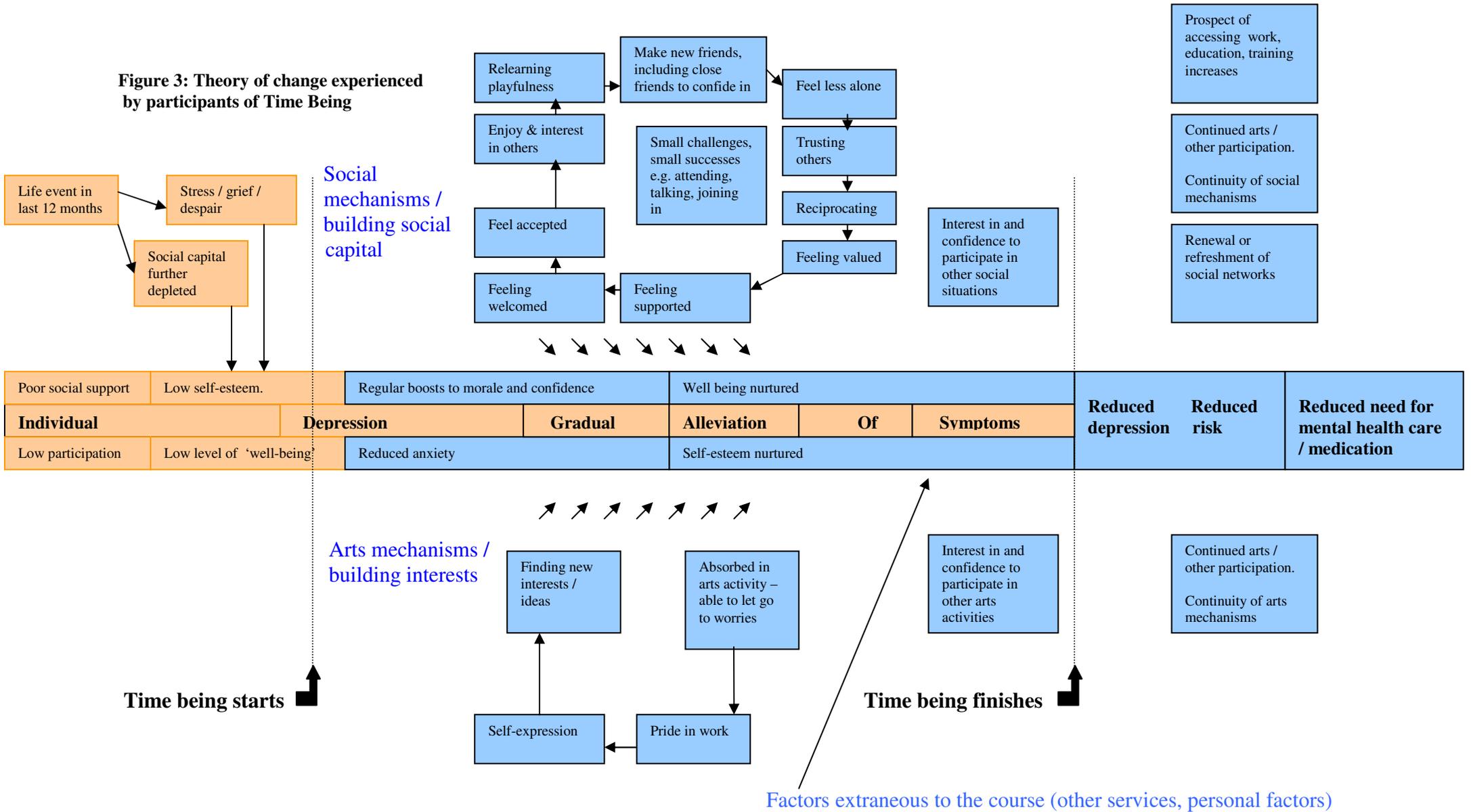
13.2 Longer term

In the longer term, it is anticipated that some of these benefits – small steps or achievements made on the course may have longer lasting effects. For example, overcoming personal social inhibitions in the environment of the course, can, crucially, provide access to social capital in the present and longer term through enhanced overall confidence to participate. Stimulation of participants' interest in arts based activities during the course may stimulate interest in continuing with participation in the arts after the course.

Some of the personal social capital, self-esteem and self-confidence built during the course may extend beyond the course; certainly where participants have discovered mutual interests and become friends, the chances of this are good. Where participants find such participation is enjoyable and where they find opportunities to participate in arts or other enjoyable social or vocational activities beyond the course, there will be further scope for personal social capital to be extended. Participants may feel confident enough to re-engage with previous social networks and positive experiences with the group or the arts may provide sufficient confidence or interest for the individual to pursue further opportunities in the arts or in other areas. And where such social capital is sustained or renewed, individuals may continue to benefit from stress buffering or main effects.

An initial model of the course that incorporates some of these concepts is shown in Figure 5 below. As noted earlier, it will be helpful to investigate the experiences of different sub-groups of individuals. Highlighting the potential mechanisms of change for the key emergent groups will be one of the products of the investigation, as will identifying the other factors that may have contributed to any observed changes in depression such as other forms of support, treatment and care received by participants.

Figure 3: Theory of change experienced by participants of Time Being



13.3 Course delivery issues that may affect the course mechanisms

Finally we consider in some of features of the design, delivery and organisation of the course that might be supportive of these mechanisms and those which might be unsupportive.

13.3.1 Heterogeneity of groups

The inclusion criteria will limit the heterogeneity of the groups to some degree, as will the self-selecting nature of the sample (which is described in the next section). We do not know enough yet about the group that will result from these processes. We will be interested to explore how the resulting samples for each group and group dynamics affect the way the course works, and will investigate this by asking artists to record their perceptions of the group dynamics of each course (described in section 5). We will identify how self-selection has affected the nature of the resulting sample, by monitoring the sample recruitment process, and exploring the results of such monitoring in focus groups with artists and the Primary Care Mental Health Team (these processes are, respectively, described in section 4 and 5).

Managing diversity also presents challenges for the artists in the delivery of the course:

“...We have also to recognise that there is also a wide range of abilities represented. Some are professionals with teaching experience in some of the arts offered, whilst others have mild learning disabilities or problems with co-ordination arising from physical or medical conditions e.g. stroke. Meeting the needs across this spectrum is not easy...we also have to acknowledge the internal dynamics of the groups i.e. how vulnerable individuals react to one another in this new and relatively unfamiliar situation”

Artist, Healing Arts

13.3.2 Location

Whilst it is a Primary Care Trust service, locating the course in a community setting has distinct advantages over a medical setting. The location of the course in busy community based arts centres may stimulate a non-stigmatising culture and ethos for the course, and will familiarise participants with the local arts scene, which may facilitate their continued participation after the course (see Everitt and Hamilton, 2003).

13.3.3 Sustainability

Heenan (2006) found that participants “*were frustrated that they were given a taste of hope but when the course ended they were largely on their own or back to traditional forms of medication and intervention*”. Unlike on-going arts-in-health projects in the community such as those described by Everitt and Hamilton, Time Being is time limited. One of its aims is to lead onto further forms of participation and for continued benefits to accrue to participants after the course has finished. It will therefore be important to examine how and how successfully efforts to link people into further forms of participation have been.

SECTION 4: SAMPLING AND RECRUITMENT OF PATIENTS

Time Being is intended for people who are experiencing mild to moderate depression and who have low personal social capital. Social capital in the context of this study is taken to mean limited or poor quality social or emotional support and social networks and limited social or community participation. The selection of this group from within the Primary Care Mental Health Team (PCMHT) client base is based on the theoretical framework that has been developed (see Section 3) the development of which aimed to identify those groups with substantial potential capacity to benefit from the course. It is contended that whilst people in this group may be in receipt of medication or psychological support, their social circumstances limit their ability to recover fully from depression through these means, and that without change in their social lives, they are most vulnerable to further depressive episodes.

The PCMHT will be the source of all participants for Time Being. The PCMHT will identify clients who may be suitable for participation and provide them with information about the course. Clients wishing to access the course will be required to contact the Local Principal Investigator (LPI), Jacqui Ager, for further information, and/or to arrange an introductory meeting (described below).

The inclusion and exclusion criteria in Table 7 below incorporate psychological, sociological, service, and personal criteria. Patients will be assessed against these criteria by the PCMHT.

Table 7: Inclusion and exclusion criteria

Criteria for inclusion	Criteria for exclusion
<ol style="list-style-type: none"> 1. Mild to moderate depression according to the World Health Organisation DSM criteria (see section 11.1 for details). With or without anxiety. 2. Low social capital affecting recovery/ability to deal with depression i.e. either or both of the following: <ul style="list-style-type: none"> • Perceives available social support (i.e. confiding relationship, friends and family) to be limited or of poor quality; • Not participating in social life (work, training, volunteering/caring, hobbies/clubs/sports, going out and ‘socialising’, or involved in community organisation). 3. The mental health needs of the client are within the scope of primary care. 4. Openness to idea of engagement with creative activity. 5. Able to function in a group. 6. Able to make own arrangements to travel to attend weekly workshops. 	<ol style="list-style-type: none"> 1. Formal psychopathology i.e. no psychiatric symptoms beyond mild/moderate depression (and anxiety). 2. Past or present needs which would be eligible for specialist treatment in secondary or tertiary mental health care. 3. Current dependence on alcohol or non-prescription drugs.

It is intended to secure the participation of around 10 people to attend at least 8 weeks of each 12-week arts course. In order to achieve this, attempts will be made to enrol around 15 people onto each course. This is because, as with any other group requiring regular attendance, it is expected that there will be some attrition to the number of attendees.

The PCMHT recruitment process will follow five key steps:

1. PCMHT will identify patients from their caseload who meet all six inclusion criteria (see Table 7) for the Time Being course. This identification can be made on initial assessment or after further subsequent sessions. PCMHT will use their professional judgement to assess these criteria rather than specific measures, since to use measures would require the PCMHT staff to change significantly the way they work with clients.
2. PCMHT will check whether patients meet the exclusion criteria (see Table 7).
3. PCMHT will mention the Time Being arts course and associated research to those patients who meet the inclusion criteria but not the exclusion criteria. PCMHT will provide patients with a **Time Being leaflet**, supplied by Healing Arts, drawing their attention to the days it is being held, where, and when the course starts (see Table 1 in Section 2).
4. PCMHT will complete a brief anonymous **participation rate monitoring form** relating to each person they give a leaflet and information sheet to.
5. PCMHT will send batches of completed forms on a quarterly basis to Matrix RCL. No names or ID codes will be shared.

Patients themselves will be required to make contact with the Local Principal Investigator (LPI) if they wish to obtain further information about the course. When patients contact the LPI, she will send them an information sheet about the research and subsequently arrange an enrolment interview where patients decide they wish to enrol in the course. Once the introductory meeting has been agreed, an **introductory meeting confirmation letter** will be sent to the patient, setting out the time, date and venue of the meeting, providing a location map of Jubilee stores where the meeting is held, instructions for how to get there, and a **consent form**.

13.4 Enrolment of participants (and taking informed consent)

As noted above, each patient is invited to attend an introductory meeting with the LPI, at Jubilee Stores, Newport. Jubilee Stores is the participatory arm of Quay Arts and houses a print studio, pottery, seven private artist's studios and the general workshop, where Time Being sessions run. The meeting will offer the participant the opportunity to find out more about the course before committing to join, and allows the LPI to explain the nature of the research associated with the course.

It will also allow the participant the opportunity to discuss any special needs they have. With the consent of the patient special needs will be communicated to all artists who will be involved in delivery of individual classes. In the experience of staff

involved in delivering previous similar courses on the Isle of Wight, it is believed that this meeting is reassuring for people who may be anxious about attending the group.

The meeting takes around an hour. The appointment will follow a set pattern:

1. Tour of Jubilee Stores and explanation of how the venue works. The tour will ensure that participants are already familiar with the venue before the course started.
2. The LPI will further describe what to expect during the course. It will be explained that mental health problems are not discussed within course sessions. If patients have concerns or anxieties about participation the LPI will listen to their concerns, and provide appropriate reassurance relating to the participation. The LPI can provide information on the content and skill level required to participate, and answer any questions about the course.
3. The LPI will further describe what to expect in terms of their participation in the research - i.e. that participants enrolling in the course can expect to be asked complete three questionnaires. Patients may withdraw consent to participate in the overall study at any time, but will not be permitted to enrol or to continue to participate in the arts course where they refuse to complete the baseline questionnaire. The LPI will emphasise that participants are invited to allow the researchers to request specific information from their GP as part of the research, but that this is not a requirement of participation in the course. She will take the patients completed **consent form** or will ask the patient to complete it if they have not yet done so.
4. An enrolment form will be given to the participant and explained. The participant will be asked to sign the **enrolment form** to indicate that they agree to the terms and conditions of participation in the course.
5. The LPI will complete the **participation rate monitoring form** (see below for details).
6. The patient will be given the **baseline evaluation questionnaire** (see next section) and the LPI will run through the questions with the patient, explaining the instructions, making sure the patient understands the questions and ensuring they know what to do with the questionnaire after they have finished it. Patients may wish to complete the questionnaire at the meeting, or take it away to complete at their own convenience. Patients will also be shown the follow up questionnaires (see next section for more details), and given a copy of the **in-depth interview information sheet**.

With the patient's permission, the LPI will, after the meeting, contact the relevant PCMHT staff to inform them that the patient has enrolled on the course, and will write to their GP to inform him/her (see **GP letter**).

13.5 Pilot

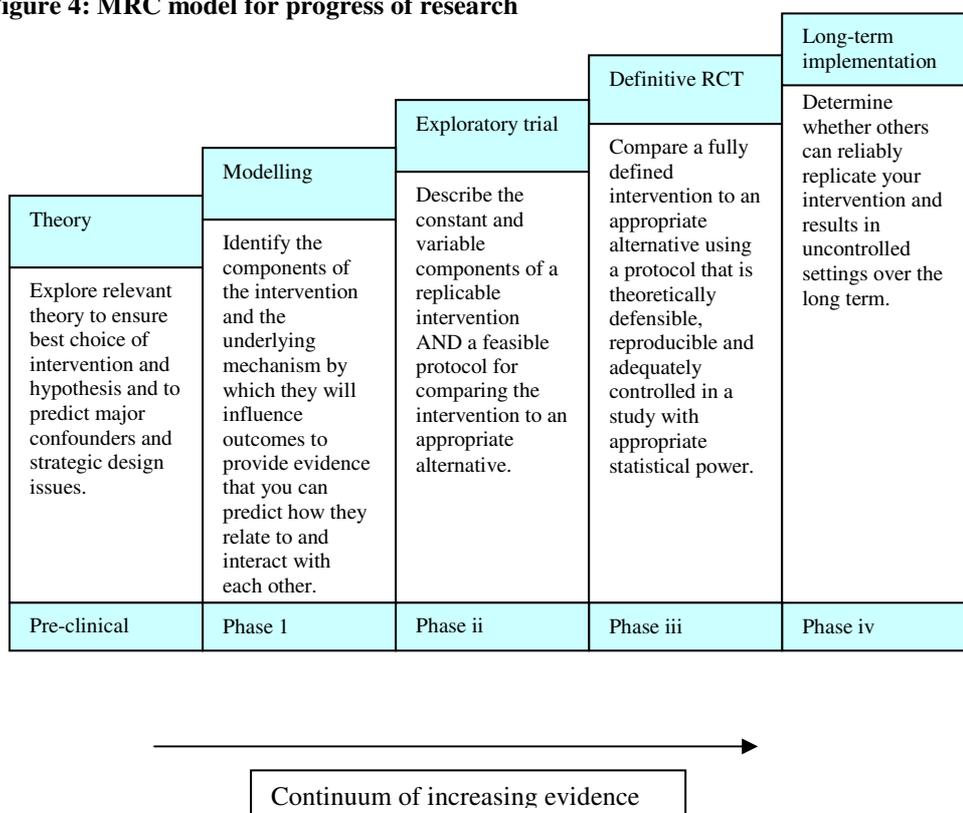
As indicated earlier, the course will be piloted through two runs of the course beginning in September 2009. This will be an opportunity to test the suitability of the procedures and arrangements for the recruitment of patients to the course and to take any remedial action necessary. The pilot will also be used to test the main data collection tools (described in Section 5).

SECTION 5: RESEARCH APPROACH

14 Overview of the research

Acknowledging that the project described in this protocol is a *socio*-medical study, the Medical Research Council (MRC) guidance on the key steps in medical research was helpful in identifying an appropriate design for the research (2000). As the diagram in Figure 4 - which is based on a diagram given in the guidance (MRC, 2000, p3) - shows, medical research should progress from theory, to modelling, through initial tests, towards controlled or randomised controlled trials prior to long-term implementation.

Figure 4: MRC model for progress of research



A conference on complex interventions in mental health recently noted that in relation to mental health research, there is a tendency for research to progress rapidly to controlled or randomised controlled trials before the other steps had been taken, with the result that the conclusions reached are misleading (NIMHE, 2004).

It is important to make sure that the evidence base for arts in health progresses at a pace which is appropriate given the state of methodological capabilities and available resources, and to avoid the risks that NIMHE warn about. In developing the design of the research, we have appraised the research literature regarding the state of methodological progress, and taken into consideration local circumstances and the resources (financial, organisational and human) available. The following points summarise this appraisal:

- The new partnerships associated with the referral of patients to the course have not been tested, nor has the effectiveness of systems for assessing eligibility of patients. The study will provide an account of how these systems have worked and how any issues might be addressed.
- The extent to which the course can be implemented consistently is not yet known – this would be required in order to progress to a trial. If the course is implemented differently each time, differences in delivery may account for differences or lack of them in overall depression scores.
- The theoretical framework has been developed for this study, and has informed the selection of appropriate measures and suitable methods. This framework must be refined, based on this research to ensure that rival accounts of observed changes can be identified, and the suitability of concepts and measures associated with them tested prior to progression to a trial.
- There is little in the way of prior research with this group (people with mild-moderate depression and low levels of personal social capital) which is needed to provide the necessary statistics (standard deviation, effect sizes) required to calculate the required sample size for a definitive quantitative trial. Furthermore since the recruitment system will be self-selecting, the potential participation rate is not yet known. In order to develop and implement a rigorous trial this information is required.
- A suitable comparison group has not been identified locally with which to compare the change in depression scores, and the local circumstances are not suitable for implementation of a control group design (i.e. current level of funding, degree of local buy in).

Based on this appraisal, it is clear that the scope of the study should correspond to the first three of the steps illustrated in Figure 3 rather than progressing to quickly to a phase iii trial. The work to develop the protocol which has involved a review of a range of policy, psychological, sociological and arts related research literature corresponds to the ‘pre-clinical’ and ‘phase 1’ steps. This work informed our initial specification of the key components of the course and delivery issues as well as the development of the theoretical framework for the course mechanisms outlined in the previous section. The next step on the continuum, which is the subject of this protocol, is a ‘phase ii’ exploratory trial – the third step.

This section of the protocol outlines the content of the exploratory trial which will be implemented with a sample of 100-150 patients. There are five key questions that the study will address:

1. Is there a clinically relevant change in self-reported depression amongst patients accessing a participatory arts course?
 - a. What is the change in self reported depression scores will be examined between a) baseline measurement (pre-course) and 13 weeks (post-course); and b) between baseline measurement and 24 weeks (post-course follow up).

2. To what extent does participation in the arts course appear to be responsible for any observed reduction in depression scores⁸?
 - a. Do theoretically relevant variables (self-esteem, well-being, social capital), which are identified as outcomes in previous qualitative studies of participatory arts, correlate with the depression measure?
 - b. Do changes in depression scores differ between types or sub-groups of patients?
 - c. What do patients believe is responsible for any observed changes during and after the course (including both course related mechanisms and other external factors such as use of other services, changes in personal or social circumstances)?
 - d. Where patients perceive Time Being to be responsible for some aspects of change, what are patients' perceptions of the effects of different forms of arts activities on their depression, self-esteem, well-being and social capital? What are patients views regarding the role of delivery aspects of the course? How do these differ for different sub-groups?
 - e. Which aspects of the course and its delivery do artists believe have an effect and why?
 - f. Are there studies that can inform our interpretation of what would have happened to these patients without having participated in the course?

3. What are the costs, and estimated cost-savings and cost-benefits of the course?
 - a. What is the cost of delivering the course?
 - b. Is there a cost-reduction in terms of use of anti-depressants, use of primary and secondary mental health care services amongst participants between a) the three months prior to baseline and the three months during the course? or b) the three months prior to baseline and the three months following the course?

⁸ In the absence of a control group, a key issue in the interpretation of information identified for the first research question will be identifying compelling explanation for observed changes. We will use a variety of data collected to address research question two, which aims to present an account of the observed change by assessing the range of factors that may have contributed to change using a variety of sources of data. These data will illuminate the range of factors that may explain changes including for example a) maturation effects (patients conditions improve naturally, rather than as a result of the course) and b) course mechanisms (social, arts based) c) instrumentality (a range of sources of benefit from outside the course contribute to change – i.e. medication, counselling, or psychological support, as well as other factors such as actual support from family, friends, change in economic circumstances / employment).

- c. If a clinically relevant change in patients' self-reported depression is observed, and based on an assumption that the change is a result of the course, what is the average cost of achieving such a benefit⁹?
- 4. How efficient and effective are new partnerships and referral arrangements associated with the delivery of the programme of courses?
 - a. How has being involved in the referral arrangements affected PCMHT working arrangements?
 - b. How effective is the self-selecting recruitment process. Are certain types of patients excluding themselves from participation? What are PCMHT staff views regarding the size and nature of the achieved sample?
 - c. How effective is the system for assessing eligibility for the course? Do PCMHT staff views of eligibility confer with patient self-report regarding levels of depression and social capital? Do PCMHT believe they have sufficient information about clients to assess eligibility?
- 5. How replicable is the intervention?
 - a. Has it been possible and appropriate to deliver the course in the same way each time it has run?
 - b. How have group dynamics, and staffing issues affected the consistency of the delivery of the course?

At the end of the study, where there is evidence of positive change in depression scores, compelling evidence that changes are to some extent precipitated by participation in the course, and where the intervention is replicable, the conditions may be appropriate for progression to a phase iii trial. However, there are additional questions, which must be addressed in considering the suitability of circumstances for a phase iii trial (see Annex 1) and this study will enable a full appraisal of these.

15 Overview of methods of data collection

The research design will incorporate a range of methods to answer the research questions. Data collection will comprise the following elements:

a. Self-completion questionnaires to collect baseline and post-course and follow up data. Each participant will be asked to complete a questionnaire at three data collection points: baseline, 13 weeks after baseline, and 24 weeks after baseline. Validated measures will be used to measure depression, anxiety, self-esteem, well-being, perceived social support and social participation. This data will contribute to answering research questions 1a, 2a, 2b, and 3c.

⁹ Evidence regarding this question will be carefully interpreted and written to ensure that readers of the report understand the strength of the evidence for an assumption of change being attributed to a patients' participation in the course.

b. *Qualitative interviews with 3 participants from four of the 12 course runs.*

Interviews will take place with participants initially at 13 weeks from baseline, and then again (with the same participants) at 24 weeks after baseline. The interviews will elicit participants' perspectives regarding the nature of problems they faced prior to participating, the changes the programme has brought about and their views on the means by which the course has brought about such changes. The sampling strategy will be a stratified purposive sample. This data will contribute to answering research questions 2c and 2d.

c. *Cost data collection.* Cost data on the implementation of the course will be obtained from the chief investigator. With patients' permission, GP's will be asked to provide data on individual clients who have been selected for the study. Data required includes visits to GP for depression, use of anti-depressant medication, referrals to PCMHT, and referral to secondary care (Community Mental Health Team). This data will contribute to answering research questions 3a, 3b, and 3c.

d. *Focus groups with PCMHT staff and artists.* Staff involved in identification and referral of patients for the course, and those involved in delivery will be invited to participate in two focus groups to discuss a) process of referral, self-selection of sample and joint working b) delivery issues and exploring outcomes. This data will contribute to answering research questions 4a, 4b, 5a and 5b.

e. *Collection of monitoring data on the delivery of the course.* Artists and the course co-ordinator will record information about the content of classes regularly in order to monitor how faithfully the course design has been followed. Additionally, information about factors affecting the delivery of the course and which may affect the mechanisms by which it works will be recorded. This data will contribute to answering research question 5a and 5b

f. *Completion of participation rate monitoring forms.* PCMHT staff will complete a form in respect of all eligible patients, and the Local Principal Investigator will complete a form for all patients who choose to access the course. These forms will incorporate basic questions about the patient to enable a comparison of the profile of the two populations to be compared. This data will contribute to answering research question 4c.

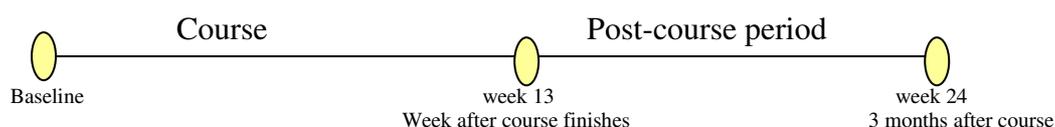
g. *Literature search.* No studies of people presenting to GPs with mild-moderate depression and low social capital were identified in the initial literature review. However, Matrix will undertake a new literature search specifically intended to identify studies with this group in order to provide an account of what would have happened had patients not participated in the course.

The detail of each of these methods is set out in the rest of this section.

15.1.1 Self-completion questionnaires to collection baseline and outcome data

In order to measure the change in self-reported depression, anxiety, self-esteem, well-being and perceived social support during and after the course, participants will be asked to complete questionnaires before they commencing the course (to measure the baseline), at 13 weeks (one week after completion of the course) and at 24 weeks (three months after the course).

Figure 5: data collection points



Baseline questionnaires will be handed to participants at the enrolment meeting (described in Section 4). The local principal investigator will run through the questions with the patient, explaining the instructions, making sure the patient understands the questions and ensuring they know what to do with the questionnaire after they have finished it. Patients may wish to complete the questionnaire at the meeting, or take it away to complete at their own convenience.

A second questionnaire (week 13) will be handed out to participants in the final week, and patients will be asked to complete and return them in the following week. They will be given stamped addressed envelopes for their response. Participants will not be asked to complete the questionnaires during the final session since this might affect participants' responses, however, the session leader will run through the questions to ensure that participants have an opportunity to familiarise themselves with the questions and understand what is required. In particular, attention will be paid to section 7 which is the only part of the questionnaire which is different to the first questionnaire. Section 7 asks participants to indicate whether they believe that Time Being was helpful to their depression, anxiety, well-being, self-esteem, and social capital. Participants will be given a telephone number to call if they have any difficulties completing either of the follow up questionnaires.

A third questionnaire (week 24) which is the same as that used at week 13 will be mailed to participants, with a stamped addressed envelope for their response. An incentive will be offered to participants to complete the second and third questionnaires.

The use of self-completion measures is a pragmatic and efficient form of data collection. Due to the sensitive nature of the data, it is also the most appropriate means of measurement of these concepts outside of an informal diagnostic interview. The tools that have been developed for the study incorporate 'gold standard' validated measures. All have been designed and validated for self-completion, rather than face-to-face interview. Use of self-completion tools rather than face-to-face interview allows interviewees the opportunity to record their true feelings, confidentially,

outside of a social context. This should result in a reduced likelihood of the data being biased by ‘socially desirable’ responses.

As noted earlier, the design of questionnaires has been informed by feedback from a small group of service users were asked to comment on a similar questionnaire. Their comments on the language, content, and length of the questionnaire have been taken into account in the design of the proposed questionnaire. The questionnaires are also based loosely on the questionnaire that has been developed for community arts mental health projects by Secker et al (2006)

Reminders and a second copy of the questionnaire(s) will be sent to participants who have not returned their questionnaire within two weeks of their being dispatched.

Patients’ questionnaires will be coded before given to participants so that there will be no identifiable information on the questionnaires. A code list will be kept in a password-protected file by the Local Lead Investigator at Healing Arts whilst Matt Baumann for Matrix will store the questionnaire data.

Sample

Details of referral and enrolment of patients, and the process for obtaining informed consent is described in Section 4. All participants who enrol in the course will be included in the research sample. The anticipated sample is between 60 and 80 (based on assumption that ten courses will run with between 6 and 8 participants attending each).

Since there are no previous studies with this group which measure change of similar arts courses using the selected tools, there is no information available with which to develop a power calculation for given effect sizes, or therefore for calculation of sample size required to enable statistically significant differences to be observed with confidence. Therefore post-hoc power analysis will be used.

Post hoc calculation will involve using the obtained sample size and effect size to determine what the power was in the study, assuming the effect size in the sample size is equal to the population effect size. The study will allow us to generate a power calculation for use in any further trials of the course with this group¹⁰.

Content of questionnaires

The topics covered at each data point, are illustrated in Table 8 below. Since data at each stage will be linked, it is not necessary to repeat collection of information that is static (e.g. socio-demographic information, previous history of depression etc).

Table 8: Content of questionnaire at each data collection point

Topic	Baseline	13 weeks	24 weeks
Socio-demographic information		Not collected	Not collected

¹⁰ The power of a statistical test is the probability that the test will reject a null hypothesis when the hypothesis is false. Three elements are required for a power calculation: the statistical significance criterion used in the test; the effect size (i.e. the size of the difference or the strength of the similarity) in the population; information on the sensitivity of the data.

Work / training intentions & status	👍	👍	👍
Long term or limiting health or mental health	👍	Not collected	Not collected
Previous experience of depression and family history of depression	👍	Not collected	Not collected
Serious life events	👍	Not collected	Not collected
Depression and anxiety	👍	👍	👍
Self-esteem	👍	👍	👍
Well-being	👍	👍	👍
Use of primary care services, medication, and use of other services	👍	👍	👍
Social capital 1: Perceived social support	👍	👍	👍
Social capital 2: Social Trust	👍	👍	👍
Social capital 3: Social participation	👍	👍	👍
Aspiration for participation in course	👍	Not collected	Not collected
Open text comments on experience of participating in Time Being	Not collected	Not collected	👍
Continued participation in arts	Not collected	Not collected	👍
Ranking of factors contributing to changes.	Not collected	👍	👍

Measurement

In addition to basic socio-demographic questions, the key concepts in the above table will be measured using the following tools:

Serious life events

This will be measured using the List of Threatening Events (Brugha et al 1985; Brugha & Craig, 1990). This list has been used in a number of studies since, for example by Prince et al (1997).

Depression/anxiety

There are a large number of established measures of depression and anxiety. The Hospital Anxiety and Depression Scale (HADS) is intended to detect and assess severity of mild to moderate depression and anxiety in inpatient or outpatient (including primary care) settings. Anxiety and depression are assessed as separate components, each with seven items that are rated from 0 (no problem) to 3; scores are totalled for each component. A score of <7 in a component is taken as a normal result; a score of 8–10 indicates mild symptoms; 11–14 indicates moderate symptoms; and 15 or more indicates severe symptoms. The scores for the two components can also be added together to give a composite anxiety–depression score. The HADS is validated for research use and is used internationally, which will facilitate comparison of the findings with other studies where appropriate (Zigmond & Snaith, 1983; Herrmann C 1997; Bjelland et al 2002). The HADS is also one of the three tools recommended by the Care Services Improvement Partnership (CSIP) for use by GPs to measure depression as part of the Quality and Outcomes Framework (CSIP 2006).

Self-esteem

Self-esteem will be measured using the Rosenberg Self-Esteem Scale (Rosenberg, 1965). It is generally accepted as the standard with which other measures of self-esteem are compared. It includes 10 items that are scored using four-point response. The scale is short, and easy to complete. It has been widely validated for use in research with acceptable reliability and validity. The Rosenberg Self-Esteem Scale is perhaps the most widely used self-esteem measure in social science research.

Well-being

Well-being will be measured using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) developed in 2006 (NHS Health Scotland, University of Warwick and University of Edinburgh, 2006). The WEMWBS has been developed to improve upon the Affectometer 2. It is a 14 positively worded item scale with five response categories from 'none of the time' to 'all of the time'. It covers most aspects of positive mental health currently in the literature, including both hedonic and eudaimonic perspectives: positive affect (feelings of optimism, cheerfulness, relaxation), satisfying interpersonal relationships and positive functioning (energy, clear thinking, self acceptance, personal development, mastery and autonomy). It does not include items specifically on life satisfaction, but hedonic well-being is well represented. Items are summed to give an overall score that can be presented as a mean score or graphically.

Use of services / medication

A small number of questions will measure use of services and medication during the previous 3 months. These questions are based on the questionnaire designed by Secker et al (2007) for use in evaluation of arts in mental health projects.

Perceived Social Support

A number of authors in the literature have found that perceived support correlates more highly with mental health than actual support. This will be measured using the Multidimensional Scale of Perceived Social Support (Zimet, Dahlem, Zimet & Farley, 1988)

Social trust

Social trust will be measured using two items used by Hyppa and Maki (2002) in a study of community participation and health.

Social participation

Few validated self-completion measures relating to social participation exist. Social participation will be measured using a small number of questions devised specifically for this study. The measure includes both associational, friendship, cultural and hobby based forms of participation. This selection reflects key concepts of participation relevant to community health identified by Hyppa and Maki (2002) and adapts some questions used by Lindström et al (2003).

Ranking of factors contributing to change

In the second and third questionnaires, participants will be asked to comment on the contribution of the arts course to changes in their social and mental health. Secker et al (2007) used this approach in their recent study of arts-in-mental-health projects to

address the lack of control/comparison group. The findings will be cross-referenced with results of the qualitative research with participants.

Pre-testing and piloting the questionnaire

The design of the questionnaire has been informed by feedback from participants of previous arts in health courses run on the Isle of Wight. We obtained feedback on a similar questionnaire designed by Secker et al (2006). We have not yet obtained feedback or pre-tested the questionnaire on a group of participants. We have largely used validated measures in the tool, but there are two sections of the questionnaire that have been specially designed for this study. Pre-testing will be important, in particular for the two new sections, and piloting is important to test response and completion rates at each data point.

Pre-test

Participants understanding of questions and responses to particular items will be tested with around six patients prior to the commencement of the pilot. We will assess:

- Ease of use of the questionnaire and length;
- Clarity and understanding of the instructions and questions;
- Sensitivity of the issues and how it feels to read and respond to the questions;
- Testing of the adequacy of the operationalisation of social participation;
- We will test the reliability of the social participation inventory through a simple test-retest method with the six participants on this inventory;
- Feedback on the section of the questionnaire that examines participants' views of the role of Time Being in any change.

Pilot

The effectiveness of the survey procedures and the questionnaire response and completion rates will be tested in September 2007 when two pilot runs of the Time Being course will be undertaken. We will also examine (with around 6 participants) the extent to which changes in scores on the social participation inventory reflect participants' views of any change in their level of social participation.

15.1.2 Qualitative interviews with course participants

Three participants from the final four runs of Time Being will be invited to participate in qualitative interviews at two time points – at 13 weeks from baseline and 24 weeks from baseline. A total of 24 interviews will be undertaken (i.e. 12 patients).

The interviews will elicit participants' perspectives regarding the changes that may have occurred in their mental health and social circumstances during and after the course. The interviews will explore the range of factors that may have led to such changes including course and non-course factors such as the use of medication, other services, life changes unconnected with the course in order that an unbiased account of change can be obtained.

A theoretical sample will be used (Ritchie and Lewis, 2003). We will identify specific sub-groups of interest after the first six course runs. Up to three sub-groups of interest

will be identified following preliminary analysis of questionnaires from the first six course runs.

Recruitment will be achieved by post. Individuals will be invited to participate by letter, and will be sent an **in-depth interviews research information sheet** and **second consent form** specific to this aspect of the research. Patients will be invited to opt-in to participation.

Interviews, which will be tape recorded are expected to last no longer than 60 minutes. Interviews will take place in a community venue such as Jubilee stores in Newport.

Audiotapes of the interviews will be transcribed in full and these will be stored securely in password protected files. Transcripts will be coded to protect the identity of patients. A code list for the interviewees will be stored in a password-protected file by Matt Baumann.

15.1.3 Cost data collection

This section sets out the data that will be used to calculate costs, cost-savings, and cost-benefits.

Costs

Average costs per client for participation in the arts course will be calculated using information provided by the Chief Investigator at the end of the course. This will include all costs and overheads involved in recruiting patients to the course, and running the course divided by the number of patients who have participated fully.

Cost-savings

Our approach to measuring cost-savings will be determined from a government's cost saving perspective using a top-down approach in measuring cost.¹¹ This is in keeping with the Treasury ISB criteria for identifying the potential for financial savings arising from projects. The timeframe of the analysis will be short run.

Savings in costs to the Trust arising from the course will be measured using information about participants' use of anti-depressants and participants' use of mental health services in primary care in the three months prior to, during and after the course. Data to be collected about each individual participant is set out in table 9. With patients' permission GPs will be asked to provide this information in a coded format to the Lead investigator who will forward this information securely to Matrix.

¹¹ The valuation of effect outcome can adopt a range of perspectives, such as government, program participant, and society. Due to the scope of research, the funding and resources available to the project, we will focus our analysis to measuring the government's perspective. The top-down (gross costing) technique spreads measures of aggregate costs, such as budgets, across the units of throughput unlike the bottom-up (micro-costing) approach, which calculates the amount of resources required to deliver units of an intervention. The top-down approach will provide an approximate measure and is less resource intensive.

Although, other variables, such as indirect costs due to productivity and health related (physical and psychological) losses, and employment gains (if any) are important for conducting a comprehensive analysis, this is beyond the scope of this project.

Table 9: Data at individual client level for the economic analysis

Medication
Cost / level of anti-depressant medication prescribed in the three months prior to accessing Time Being.
Cost / level of anti-depressant medication prescribed in the three months during participation in Time Being.
Cost / level of anti-depressant medication prescribed in the three months after leaving the Time Being programme.
Consultation with GPs
Number of consultations with GPs regarding depression prior in the three months prior to accessing Time Being.
Number of consultations with GPs regarding depression in the three months during participation in Time Being.
Number of consultations with GPs regarding depression in the three months after leaving the Time Being programme.
Consultation with PCMHT
Number of consultations with PCMHT staff regarding depression in the three months prior to accessing Time Being.
Number of consultations with PCMHT staff regarding depression in the three months during participation in Time Being.
Number of consultations with PCMHT staff regarding depression in the three months after leaving the Time Being programme
Referrals to Community Mental Health Team
Number of referrals to CMHT for depression in the three months prior to accessing Time Being.
Number of referrals to CMHT for depression in the three months during the three months of participation in Time Being.
Number of referrals to CMHT for depression in the three months after leaving the Time Being programme

In order to translate the above data into costs, we will obtain the data in Table 10.

Table 10: Service costs data

Average cost per patient for a GP consultation (for depression).
Average cost per patient for PCMHT counselling (for mild-moderate depression).
Average cost per patient for antidepressant medication.
Average cost per patient for referral to CMHT.

Cost benefits

Additional information required for assessing cost benefits is actual depression change scores for each participant. Average change can then be juxtaposed with the costs associated with delivery of the course to identify cost per point improvement in depression score.

15.1.4 Focus groups with referring and delivery staff

A focus group with PCMHT staff will be undertaken at the end of the pilot course.

At the first focus group the following referral related issues will be explored:

- Workload issues in identification of patients and assessment of eligibility;
- Ability of the team to assess eligibility (including availability of required information).
- The achieved sample and explanations for its size and characteristics
- The impact of the self-selecting nature of the sample

A second focus group will be undertaken in November 2009 separately with PCMHT staff and artists (during the final run of courses). The topics to be explored are set out below:

PCMHT focus group:

- Feedback on doing recruitment
- Impact of recruitment on PCMHT working procedures?
- Issues in recruitment – e.g. has information required to assess eligibility been routinely available to PCMHT? What special arrangements have had to be made?
- Take up of programme by different patients and self-selection/exclusion
- What sort of information / feedback are you getting on the programme?
- What might be done to improve arrangements (e.g. burden of work involved in recruitment, improved information on eligibility, increase take up of the programme, information flow from PCMHT – arts programme and back.

Artists focus group:

- Discussion of course content
- Variation in course content between programmes
- Take up of the course
- Artists' interpretation of what Time Being does for patients and how
- Artists' perception of who the course works best for and who it doesn't in terms of mental health and social outcomes? and why?
- What does it do consistently for patients? What does it achieve sometimes for patients? why?
- Artists' interpretation of how the course works?
- What challenges in delivery?
- What makes for the best results in a course?

The second focus group will be audio taped and transcribed in full for thematic analysis. Staff will be invited to the second focus group by letter, and will be provided with an **Information Sheet** relating to the research.

15.1.5 Collection of monitoring data on delivery

Since the course is multi-faceted and delivered by a range of artists it is important to assess the extent to which the course has been implemented faithfully according to

design, as well as seeking an understanding from artists affecting the implementation which will be obtained in the focus groups.

A range of information will be collected on a **session record form** and a **course review form**.

Session record form

Each artist will complete this after each session. The artist will record:

- Details of the work undertaken (what activities).
- Does what was delivered differ from what was planned?
- What did work well and why;
- Did anything not seem to work well? Why? What can be done?
- Details of the group dynamics and how they affected delivery
- Other circumstantial factors affecting the delivery.

Course review form

This will be completed by the course co-ordinator in conjunction with artists involved in delivery at the end of each course. The form will allow the co-ordinator to provide an overview of the whole course using the same categories used in the artist record form.

The data collected using these forms will also be an aid-memoir for participants of the focus groups.

15.1.6 Completion of participation rate monitoring forms.

Identifying how successful the recruitment process is in attracting those who are eligible to participate will be fundamental to our ability to understand the efficiency and effectiveness of the self-selecting sample system.

We will compare the profile of people who enrol in the course, with the profile of patients who are eligible and who have been given leaflets, in order to identify any significant differences. In order to do this, it will be necessary to monitor the profile of patients in each group. An anonymous **participation rate monitoring form** will be completed for eligible patients by the PCMHT, and again by the LPI on enrolment.

The form obtains information on each client including:

- Sex;
- Age;
- GP surgery;
- Working status
- Level of interest in participating;
- Likely factors that might prevent participation.
- Preferences for time/days for attendance

16 Analysis

In this section we set out the preliminary outline for the analytical framework – using the research questions and contributing sub-questions set out previously to provide a basic structure. Each research question will be answered by the analysis performed on the relevant sub-questions.

1. Is there a clinically relevant change in self-reported depression amongst patients accessing a participatory arts course?

- a. *What is the change in self reported depression scores will be examined between a) baseline measurement (pre-course) and 13 weeks (post-course); and b) between baseline measurement and 24 weeks (post-course follow up).*

Analysis of self-completion questionnaires: HADS-D scores range from 0-21, with higher scores representing higher levels of depression. Rahimi-Ardabili (2006) suggests that scores can be ranked as normal (0–7), mild (8–10), moderate (11–15), and severe (16–21). A recent study of psychological interventions with depressed patients, which have measured change using the HADS-D identified a change of between 4-6 points and the authors concluded that increasing the number of sessions achieved no further benefits¹². This may be a useful initial benchmark for our study, but we will investigate the findings of other studies and in particular try to identify studies of groups similar to ours. Our analysis will use a within-subjects, single factor, analysis of variance (ANOVA), with time of measurement (baseline, week 13 or week 24) as the independent variable, and rates of depression (as measured by HADS scores) as the dependent variable. ANOVA is preferred over the use of matched t-tests for preliminary analysis, to reduce probabilities of a Type I error arising from multiple comparisons. Where differences are found, matched sample t-test may be used, if considered appropriate, to assess the difference at baseline-13 weeks, baseline to 24 weeks, and 13 weeks to 24 weeks.

2. To what extent does participation in the arts course appear to be responsible for any observed reduction in depression scores?

- a. *Do theoretically relevant variables (self-esteem, well-being, social capital), which are identified as outcomes in previous qualitative studies of participatory arts, correlate with the depression measure?*

Analysis of self-completion questionnaires: The theoretical framework proposes that the course will result in increases in self-esteem, well-being, perceived social support, and actual social participation, and that improvement in these areas may be directly related to improvement in depression. We will investigate covariance of these variables initially using correlation, using mean change scores for self-esteem, perceived social support, social participation, depression and well-being scores. We expect reductions in HADS-D resulting from the course to correlate with increase in self-esteem, well-being, perceived social support, and social participation measures. We expect increases in well-being scores to positively correlate to these measures.

¹² www.lanpdc.scot.nhs.uk/achievements/posters_clc_2005/frances_ford.pdf

b. Do changes in depression scores differ between types or sub-groups of patients?

Analysis of self-completion questionnaires: As noted in the theoretical framework, certain factors in depression may influence changes observed in depression scores. As outlined, the main sub-groups we wish to investigate are:

- Previous life events;
- Previous depressive episode;
- Family history of depression;
- Depression only or depression with anxiety;

To analyse the effect of these factors on change in depression scores we will firstly measure the correlations amongst all variables. This will show whether these variables are correlated with HADS-D scores and each other. Secondly, multiple regression will be used to examine correlations in more depth. All variables outlined above will be entered into a stepwise regression model as independent variables, and change in HADS-D scores will be entered as the dependent variable. This will show whether the effects of any variable (accounting for the effects of any other variable) will individually predict the change in depression score. We will also enter other participant variables (such as age/sex/initial mild or moderate depression) and treatment variables (such as use of medication, use of primary care and other services which) to examine their contribution to observed change in depression scores.

In addition to contribute to our understanding of the reasons for the changes in depression scores identified, these analyses will facilitate our identification of interesting sub-groups to be included in the qualitative strand of the study.

c. What do patients believe is responsible for any observed changes during and after the course (including both course related mechanisms and other external factors such as use of other services, changes in personal or social circumstances)?

Analysis of qualitative interviews with participants: The transcripts of interviews with 12 participants will be analysed to explore the range of factors that emerged during interviews relating to observed changes in depression, self-esteem, well-being, and social capital. Each of the interviews will be analysed thematically.

d. Where patients perceive Time Being to be responsible for some aspects of change, what are patients' perceptions of the effects of different forms of arts activities on their depression, self-esteem, well-being and social capital? What are patients views regarding the role of delivery aspects of the course? How do these differ for different sub-groups?

Analysis of qualitative interviews with participants: Where patients have identified Time Being as a factor in the changes they have experienced, the interviews will be further analysed to explore in detail the nature of the changes observed, the types of ways in which Time Being may have brought about changes. The three – four sub-groups that have been sampled will be compared and contrasted.

e. Which aspects of the course and its delivery do artists believe have an effect and why?

Analysis of focus groups with staff: The transcripts of the second focus group will be analysed thematically to understand artists' views regarding the contribution of the course.

f. Are there studies that can inform our interpretation of what would have happened to these patients without having participated in the course?

Analysis of previous studies with this group: The literature search will seek to identify relevant studies in order that evidence of the counterfactual may be incorporated into the account of the observed change.

3. What are the costs, and estimated cost-savings and cost-benefits of the course?

a. What is the cost of delivering the course?

Analysis of cost data: Cost of delivering the course per patient will be assessed.

b. Is there a cost-reduction in terms of use of anti-depressants, use of primary and secondary mental health care services amongst participants between the three months prior to baseline and the three months during the course, or between the three months prior to baseline and the three months following the course?

Analysis of cost data: Average costs per patient will be compared in the three different periods

c. If a clinically relevant change in patients self-reported depression is observed, and assuming the change is a result of the course, what is the average cost of achieving such a benefit¹³?

Analysis of cost data and questionnaire data: The average cost per patient for each point improvement on the depressive sub-scale of the HADS will be identified.

4. How efficient and effective are new partnerships and referral arrangements associated with the delivery of the programme of courses?

a. How has being involved in the referral arrangements affected PCMHT working arrangements?

Analysis of focus groups with staff: Detailed notes of the first focus group will be taken summarising the issues arising from discussions with PCMHT regarding workload issues. These topics will be revisited in the second focus group with PCMHT which will be taped and transcribed and analysed thematically.

¹³ Evidence regarding this question will be carefully interpreted and written to ensure that readers of the report understand the strength of the evidence for an assumption of change being attributed to a patients' participation in the course.

b. How effective is the self-selecting recruitment process – are certain sub-groups excluding themselves? What are PCMHT staff views regarding the reasons for the achieved sample?

Analysis of participation rate monitoring forms: The profile of participation rate monitoring forms completed by PCMHT staff (for all eligible patients) will be compared with those completed by the Principal Investigator, to identify if some groups of patients are self-excluding.

Analysis of focus groups with staff: The write up of the first focus group will be analysed to examine PCMHT staff views of the size, representativeness and nature of the sample including exploring reasons for any differential participation rates between sub-groups. The second focus group with PCMHT which will also explore these issues will be taped and transcribed and analysed thematically

c. How effective is the system for assessing eligibility for the course? Do PCMHT staff views of eligibility confer with patient self-report regarding levels of depression and social capital? Do PCMHT believe they have sufficient information about clients to assess eligibility?

Analysis of questionnaires: The sample obtained will be examined using the self-completion questionnaires to explore its characteristics and checked against the eligibility criteria to examine whether the sample is as expected.

Analysis of focus groups with staff: The write up of the first focus group will be analysed to understand PCMHT views regarding the information available to them to assess eligibility, the factors which have affected their ability to identify participants and to explore any unanticipated characteristics of the sample. The second focus group with PCMHT which will also explore these issues will be taped and transcribed and analysed thematically

5. How replicable is the intervention?

a. Has it been possible and appropriate to deliver the course in the same way each time it has run?

Analysis of course review forms: The course review forms and artist review forms will be analysed to quantify the extent to which the course has been implemented faithfully each time. Additionally these issues will be explored in the analysis of focus groups with artists.

b. How have group dynamics, and staffing issues affected the consistency of the delivery of the course?

Analysis of course review forms: The course review forms and artist review forms will be analysed to explore the delivery issues affecting replicability.

Analysis of focus groups with staff: The transcripts of the focus group with artists will be analysed thematically to understand artists' views regarding the factors that have affected the delivery of a consistent programme.

SECTION 6: ROLES, RESPONSIBILITIES, RISKS & OUTPUTS

17 Roles & responsibilities

Funders

HM Treasury are funders of the programme 'A lifetime's Health Delivered Creatively'. This project is one of three projects that are being undertaken within this programme, within the Isle of Wight NHS PCT. The project was awarded funding through a competitive bidding exercise, which assessed projects in terms of value for money and against specific criteria relating to the degree and potential effect of innovation, the potential benefits to patients and to efficiency of service delivery, and the robustness of project management.

Programme sponsors

The programme sponsors for 'A lifetime's Health Delivered Creatively' are the Department for Culture, Media and Sports, and the Department of Health (via the public health department of the Government Office for the South East). The programme sponsors are actively involved in monitoring progress of the project and will receive a biannual report from the project committee.

Project sponsors

The project sponsorship has been delegated by DCMS and DH to the Isle of Wight NHS Primary Care Trust. The Trust will fulfil the specific duties of sponsorship incorporated in the Research Governance Framework for Health and Social Care.

Project committee

The project committee consists of Matt Baumann (Matrix Knowledge Group), Guy Eades (Healing Arts, Isle of Wight NHS PCT), Tara Dean (Research and Development Support Unit, Isle of Wight NHS PCT). The committee will report regularly to the project sponsor. It is responsible for:

- Ensure adequate monitoring of the overall delivery of project;
- Assessing issues and risks to the project success and proposing remedial action;
- Receiving regular reports from Matrix RCL on progress of the research.

Chief Investigator

The Chief Investigator is Guy Eades, Director Healing Arts, Isle of Wight NHS Primary Care Trust. He is responsible for:

- Overall project management;
- Management of local delivery of the course;
- Management of the relationship with the funder and the programme and project sponsors;
- Management of the contractual arrangements between Matrix RCL and the Trust for the delivery of research services;
- Organising project committee meetings and for the annual report on the research to the LREC.

The Chief Investigator delegates responsibilities for the design of the research and for ensuring the quality of research and its outputs (set out below) to Dr Elaine Stewart, Matrix Knowledge Group.

Local Principal Investigator

The local Principal Investigator is Jacqui Ager. Jacqui co-ordinates *Time Being* and is employed by Healing Arts (Isle of Wight NHS Primary Care Trust). Jacqui is responsible for:

- Liaising with the Primary Care Mental Health Team regarding referral of patients;
- Receiving calls from patients about Time Being Research Programme, and arranging 'introductory meetings' with patients;
- Dispatching information sheets, introductory meeting confirmation letters and consent forms;
- Undertaking introductory meetings - ensuring patients understand the terms of participation in the research and for taking informed consent;
- Ensuring that patients have the opportunity to ask any questions and to be reassured about the nature of participation;
- Giving patients the baseline evaluation questionnaire and taking them through the questions and making sure they know what to do;
- Enrolling patients onto the Time Being programme;
- Holding securely the patient contact file, consent forms and site file
- Sending letters to patients GPs to inform them that the patient has enrolled on the programme;
- Ensuring the completion of anonymised participation rate monitoring forms;
- Ensuring that participants have completed and submitted the baseline evaluation questionnaire prior to commencing Time Being;
- Monitoring artists completion of session record sheet;
- Meeting with artists, reviewing session record sheets for each course;
- Completion of course review form;
- Obtaining informed consent for qualitative interviews and for arranging these interviews
- Arranging hand out to course participants of the outcome questionnaires at 13 weeks and mail out at 24 weeks;
- Obtaining medical data from GPs
- Attending the project committee as required.
- Reporting progress of the to the Chief Investigator;
- Liaising with Matrix Knowledge Group.

Matrix Knowledge Group

Matrix is responsible for:

- Design of the research and all research tools;
- Data protection of all data held by Matrix.
- Undertaking depth interviews with patients;
- Arranging and facilitating focus groups;
- Obtaining reports and articles on similar studies for comparative purposes;
- Undertaking data analysis, and drafting the outputs;
- Facilitating and participating in the project committee.

Primary Care Mental Health Team staff

PCMHT staff are responsible for:

- Identifying clients who meet the inclusion criteria and who don't meet the exclusion criteria;
- Provision of a leaflet about Time Being;
- Completion of an anonymised participation rate monitoring forms;
- Participation in two focus groups.

Healing Arts

Healing arts team are responsible for:

- Delivery of the arts course;
- Monitoring their own delivery of the course;
- Completion and submission of session record sheet;
- Participation in one focus group.

GP surgeries

GPs are responsible for:

- Providing patient data on medication and service use for patients in the sample.

18 Project risks

The main risks to the project success lie in the area of recruitment of patients. These risks and action to monitor and address them are set out in Table 11.

Table 9: Recruitment risks

Risk	Risk likelihood & impact	Description	Action
Overall low numbers of patients eligible for course.	L: Low I: High	We have been given an estimate from one of the Primary Care Mental Health Team staff of the numbers of clients who may be eligible for the course. One of the workers considers that she will have around 8 per month. Assuming that each worker has the same profile of clients we expect that the PCMHT will identify 40 eligible clients per month. Since there is either three or four months between start dates for each course and since PCMHT will continue to identify clients we estimate that around 120 clients will be identified for each course.	Monitor flow of patients during pilot.
Insufficient numbers of clients call to join the course.	L: medium to high I: high	The PCMHT are not willing to refer clients directly to the course, or to provide contact details for their clients. Therefore the evaluation is dependent upon clients' self-selection.	The main way in which this issue can be addressed is by ensuring that the leaflet is very attractive. The leaflet will provide brief details and clients will be required to call the course co-ordinator to receive a course information pack. It is believed that this approach will result in higher numbers of patients calling the number than an approach which requires patients to call for 'further information' or 'to enrol', since the option to call for an information pack requires low commitment on the part of the patient. When clients call the course co-ordinator will take the clients name and contact details and will send the pack out. The course co-ordinator will contact patients around one week later to ask if they would like to enrol. If this approach fails, the course will be advertised more widely. Monitor during pilot
Low participation rate amongst specific groups.	L: high I: low to medium	It is possible that certain groups will not access the course, despite being eligible and having the capacity to benefit, since there are risks both the evaluation, and the viability of the course as a local service of differential rates of participation. This includes:	It will be important to monitor participation in the way discussed at the end of Section 3. Actions for specific risks are set out below for each.
		a) Low participation rate of patients from the South of Island – where there is high level of mental health need.	It is not possible to deliver in a variety of areas since the community venues are located in Newport, and the logistics of organising courses in other areas would be too complex. In order to manage this risk, participants who live outside of Newport and who are on benefits will be paid travel expenses. Payment one week in arrears will be made in respect of expenses incurred by participants for the use of public transport to attend the course. Participants will be eligible to claim for expenses if they are in receipt of benefits such as unemployment benefit, income support or incapacity benefit. Proof of ticket purchase will be required. Participation of patients from different areas will be monitored.

		b) Low participation rate amongst eligible men. Previous courses that have been run have had low levels of participation amongst men	It will be important to monitor this and identify why men are not accessing the programme, if this is the case. Appropriate action to address the problem will be considered towards the end of year 1.
		c) Low participation rate amongst younger people. Previous courses have had low levels of participation of young people.	It will be important to monitor this and identify why younger people are not accessing the programme. Appropriate action to address the problem will be considered towards the end of year 1.
		d) Low participation rate amongst people with young children. There are no childcare facilities available to enable single parents or parents with young children to attend.	It will be important to monitor this and identify the level of potential demand amongst this group. Appropriate action to address the problem will be considered towards the end of year 1.
Long waiting time/wait list to attend the course during which time symptoms change.	L: Low to medium I: medium	Since the PCMHT will continue to identify patients on a rolling basis, patients who have been identified when the course has started or when both course runs are full up will have to wait for up to three months until the next course. Patients' symptoms may change during this period meaning that they may no longer be depressed or may be more depressed by the time the course starts.	It is acknowledged that some patients may have to wait for a longer period than others. Patients who contact Healing Arts to participate and who are too late to join a class will be placed on a waiting list. They will be contacted nearer the time by the course co-ordinator who will ask whether the patient is still experiencing the same issues as they were at the time they were deemed eligible by the PCMHT. It will be established whether their situation is better or worse. If the patient reports that it is substantially worse, patients must see their GP or PCMHT counsellor before enrolling. If patients rate their symptoms as much better, patients will be advised that they are no longer eligible to participate, since the course is intended for people who are experiencing mild to moderate depression. It is anticipated that this problem will affect only a small proportion of patients, however if the number of patients affected in this way is large, appropriate action to address the problem will be considered towards the end of year 1.

18.1 Outputs

- July 2010: Report on the key research questions
- July 2010: Summary report for public, staff, and participants
- July 2010: Outline protocol for a ‘phase iii’ trial of the course (where circumstances and conditions are favourable – see Annex 2 below and discussion in section 5)

18.2 Dissemination

A national conference on Arts in Health organised by Director of Healing Arts is planned where the findings of all three Isle of Wight projects (stroke, depression and childhood obesity) will be presented to an audience consisting of health and arts policy makers, health commissioners, artists and arts project staff, and researchers.

SECTION 7: REFERENCES

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ANNEX 1: GANTT CHARTS

Typical progression of the *Time Being* Course

Activity description	Activity prior to enrolment in Time Being (approx weeks)				Activity during 12 week course (weeks)												Activity after Time Being finishes.				
	-3	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15-23	24	25
Patient presents to GP with depression/anxiety	█																				
GP provides patient with leaflet about Primary Care Mental Health Team (PCMHT)		█																			
Patient contacts PCMHT and is provided with support/counselling/referrals		█																			
PCMHT assesses patient eligibility for Time Being - using inclusion and exclusion criteria		█																			
Eligible patients given leaflet about Time Being.		█																			
PCMHT completes participation rate monitoring form for each eligible patient (and send to Matrix)		█																			
Patient considers whether interested in course, and contacts course co-ordinator/principal investigator (PI)			█																		
Patient receives information sheet about the programme from the PI & can arrange to attend introductory meeting			█																		
PI sends patient 'introductory meeting confirmation letter' and consent form			█																		
Patient attends introductory meeting with PI at Jubilee Stores			█																		
Patient completes consent form, enrolment form.			█																		
PI completes participation rate monitoring form			█																		
Patients given baseline evaluation questionnaire and PI explains how to complete it			█																		
PI informs PCMHT and patients GP that patient has enrolled.			█																		
Welcoming to Time Being - all artists attend first week				█																	
Visual arts					█																
Music						█															
Mid-course arts team review							█														
Movement								█													
The written word									█												
Feedback & follow on session - participants given outcome questionnaire & session leader runs through questions																█					
Post course arts team review																	█				
Patients complete questionnaire in next week and return no later than two weeks after course																		█			
Patients sent follow up q're 12 weeks after final week of course. Patients return it to Matrix within two weeks																				█	

Overall progress of the project

Activity / Deliverables	2007		2008			2009			2010	
	Jun - Aug	Sep-Nov	Jan-Mar	Apr-Jun	Sep-Nov	Jan-Mar	Apr-Jun	Sep-Nov	Jan-Mar	Apr-July
Pre-test the questionnaire - reliability and both construct & face validity & make any necessary amendments	■									
Pilot courses 1 & 2		■								
Pilot the research tools and procedures and make necessary amendments		■								
Further development of analytical framework										
Time being courses 1 & 2				■						
First focus group with PCMHT				■	■					
Time being courses 3 & 4										
Time being courses 5 & 6							■			
Interim analysis of questionnaire data and refinement of analytical framework							■			
Time being courses 7 & 8								■		
Interviews with three participants from courses 7 or 8 at 13 and 24 weeks from baseline							■			
Time being courses 9 & 10								■		
Focus groups: 1. Artists 2. PCMHT								■		
Interviews with three participants from courses 9 at 13 and 24 weeks from baseline								■		
Transcription of interviews								■		
Request & receipt of medical data from GPs									■	
Analysis of questionnaire data									■	
First draft report & summary report										■
First draft protocol for phase iii trial of the course										■
Second draft report/summary										■
Second draft protocol										■
Final draft report										■
Final draft protocol										■

ANNEX 2: CIRCUMSTANCES REQUIRED FOR A PHASE III TRIAL

Compelling evidence from multiple sources that suggest course mechanisms are 'active' and have a beneficial effect on participants;

Compelling theory about how the course works supported by a range of evidence;

Clear testable hypotheses based on exploratory work, concerning the changes observed on key outcomes;

Clarity regarding the independent variables of most relevance, based on exploratory work undertaken as part of this protocol

Identification of a theoretically appropriate control group

Local knowledge to enable the design, development and agreement of a feasible control group design;

Evidence that the course can be reliably replicated;

Established working relationships between researchers, referring team, and course delivery team and adequate buy in to a phase iii trial;

Sufficient buy-in from all local stakeholders to a substantially greater degree of involvement and effort than is currently committed e.g. willingness to use standardised tools as part of recruitment and to enforced inclusion and exclusion criteria strictly, willingness to refer clients to the course rather than handing them a leaflet, willingness to implement a factorial design;

An established process for referral of clients;

A predictable flow of patients who meet the inclusion and don't meet the exclusion criteria;

Knowledge of the participation rates and factors affecting the participation rate; (i.e. confidence that there will be sufficient participation and knowledge of the representativeness of the group);

Knowledge of the distribution (standard deviation) of the patient group on key outcomes of interest to enable decisions about design of course and control samples to be made;

Sufficient buy in from all GP surgeries to provide required patient data;

A set of research instruments and tools, which has been tested with this group.