



Being Mindful of the Carers



Project Team:

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Summary and Keywords

“Mindfulness is both a skill and a way of living. It is about living in the here and now rather than being caught in the past or worrying all the time about the future.” (Mindfulness Scotland, 2013).

Aim

To explore the effect of Mindfulness Based Cognitive Therapy (MBCT) programme upon the health and wellbeing, dignity and respect of carers for people with dementia (PWD), in a remote and rural area.

Methodology

The programme was run over a six month period and delivered to eight carers within Argyll and Bute CHP who were recruited from the caseload of the Community Dementia Team. Sessions were delivered weekly for 8 weeks and thereafter participants were offered fortnightly and monthly maintenance sessions. Audio recorded semi-structured one-to-one interviews were carried out at baseline in order to explore the perceptions of how caring affects the participants health and wellbeing. Upon the conclusion of the MBCT programme (month 6) further interviews were undertaken to examine the perceptions of the participants of how mindfulness has influenced their health and well-being.

Analysis

Initial results showed that as a result of the caring role carers felt a sense of loss of the relationship and it difficult to make time to enjoy previous activities without feeling they were “snatching time” to do so. Upon completion of the MBCT programme carers recognised the benefits of applying mindfulness practices to their daily routine, which have been beneficial to not only their health and wellbeing but has also had an effect upon their caring role. By applying mindfulness to daily life and routine participants have felt able to value themselves and their role more and extend kindness towards themselves and their cared for person.

Key words

Mindfulness, Mindfulness-Based Cognitive Therapy (MBCT), Carers of People with Dementia (PWD), Health and Wellbeing of Carers.

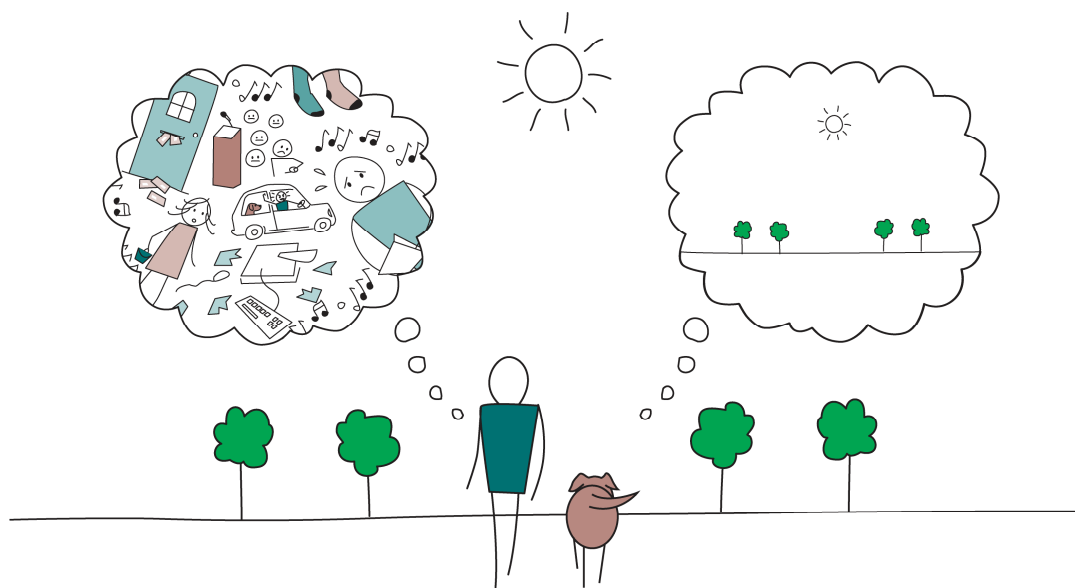
1. Background

According to the Alzheimer's Society approximately two-thirds of people in the UK with dementia are cared for in the community setting (NHS Choices, 2013). Care is often provided by family members and informal carers (Brodaty and Donkin, 2009). Many carers report being under an incredible amount of stress due to not only their loved one/relative becoming unwell and their behaviours deteriorating, but also the lack of care they experience or provide to themselves. (NHS Choices, 2013).

Many carers are unpaid and report a high incidence of depressive illnesses – approximately 30-50% of carers experience depression (Ballard, Eastwood and Gahir, 1996). Carers are often encouraged to look after themselves but it is recognised that they often feel guilt in doing so. (www.alzscot.org, 2013). Carers, for example, often find it more challenging to leave the home and their loved one leading to social isolation, physical and mental health problems (www.careserach.com.au, 2013). The majority of research points to the need to support carers to look after themselves, physically, emotionally, mentally and spiritually (www.caresearch.com.au, 2013). While training may be available to care home staff and other health professionals, there is little evidence to identify how this translates to carers within the domestic setting who may have had little or no training, and may be an older person themselves. Within this context, the possibility of providing support through mindfulness training becomes a potential model of interest.

Mindfulness practice was originally developed in East Asia and has strong correlations to meditation practices. The most recent frequently cited method of mindfulness training was developed by Jon Kabat-Zinn in the late 1970s as a Mindfulness-Based Stress Reduction (MBSR) programme (www.mindfulnet.org, 2013). Williams, Teasdale and Segal developed the Mindfulness Based Cognitive Therapy programme as a recognised treatment for people with depression. It combined Cognitive Behavioural Therapy and Mindfulness to establish a programme of Mindfulness Based Cognitive Therapy (MBCT) (www.mindfulnet.org, 2013). Essentially, mindfulness based training is aimed at teaching users to practice bringing their awareness to the present moment and experience this without judgement, showing kindness to themselves to support “balance and resilience at work and home”. (www.mindfulnet.org, 2013) MBCT “is about becoming more aware of how you think and

behave in order to help improve your life". (Collard, 2013, p. 11). MBCT has now become a recognised technique by the National Institute of Clinical Excellence in the treatment of depressive illnesses. (NICE, 2009). This project seeks to determine whether mindfulness is an appropriate and beneficial support tool to improve the health, wellbeing, personal respect and dignity of carers of persons with dementia by enabling them to employ mechanisms to reduce the stress created by their carer role.



Mind Full, or Mindful?

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2. Aim and Objectives

Aim

To pilot a Mindfulness Based Cognitive Therapy (MBCT) programme over a six month period to carers of people with dementia within the local community of Oban, Argyllshire, and to assess the impact and effectiveness of the programme upon the health and wellbeing, respect and dignity of carers within a remote and rural area.

Objectives

To Explore:

- a) The effect of mindfulness based cognitive therapy (MBCT) upon the health and wellbeing, respect and dignity of carers for people with dementia, in a remote and rural area.
- b) The effect of the role of the carer upon their health and wellbeing
- c) How carers perceive the influence of Mindfulness Based Cognitive Therapy (MBCT) with respect to their health, wellbeing, dignity and self-respect.

3. Design and Methods

Potential participants were identified from existing carer roles of people with a definite diagnosis of dementia known to the community dementia team caseload. All carers were residing with the person and providing care for their relative/partner.

An information letter and carer information sheet (see Appendix 1) was provided to enable the carer to decide whether they wished to opt in to the programme or not. The letter was sent by mail, with a reply slip and prepaid return envelope provided. The group were self-selecting. A member of the project team contacted any respondents by telephone to discuss the project further, answer any queries, and to identify any need for respite for the person with dementia. Thereafter the carer was asked to meet a member of the project team to obtain consent to the programme (see Appendix 2). Consent included permission to contact the GP should any issues/concerns arise either for the carer or the person with dementia. We advised that it is our duty of care to notify the GP or relevant stakeholder in line with Adult Support and Protection Legislation (The Scottish Government, 2007). Any potential participant, who did not consent to sharing of information with the GP or relevant stakeholder, would not be included within the programme. The programme ran over a 6 month period. The eight week Mindfulness Based Cognitive Therapy (MBCT) programme was delivered by the local dementia specialist Occupational Therapist and co-facilitated by a Community Mental Health Nurse and Dementia Advisor. The Occupational Therapist and Community Mental Health Nurse are recognised facilitators of MBCT. Each session was two hours long and a group activity. Funding was available to provide respite care for the person with dementia. This enabled the carer to attend the programme.

Mindfulness is a life skill where home practice is key to its success. However it was recognised that carers may not be able to free up time to complete all of the practice exercises. Practice was not mandatory to the complete/attend the programme. Upon successful completion participants were offered fortnightly and monthly maintenance sessions. Participants who were unable to complete the course, were offered support via the existing carer networks and the Community Dementia Team.

4. Methodology

- 1) Recruit sample
- 2) Gain informed consent
- 3) Audio recorded, semi-structured one to one interviews carried out at baseline in order to explore perceptions' of how caring effects health and well being
- 4) Delivery of MBCT sessions
- 5) Audio recorded semi-structured one to one interviews carried out at month six, after the MBCT programme in order to examine perceptions of how this has influenced health and well being
- 6) Verbatim transcriptions of recordings
- 7) Data analysis by thematic analysis for both data sets
- 8) Preparation of report

5. Ethical Considerations

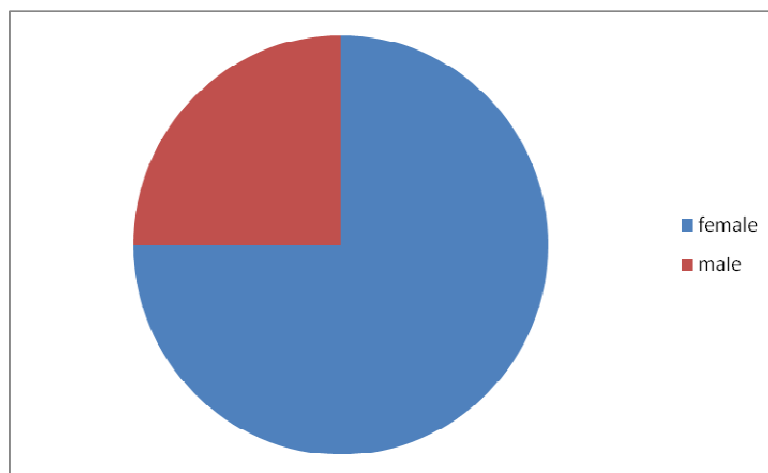
In accordance to the guidance full ethical and research & development approval was obtained from West of Scotland Research and Ethics Committee 3 and NHS Highland. (See Appendix 3).

REC reference:	13/WS/0280
IRAS project ID:	140320

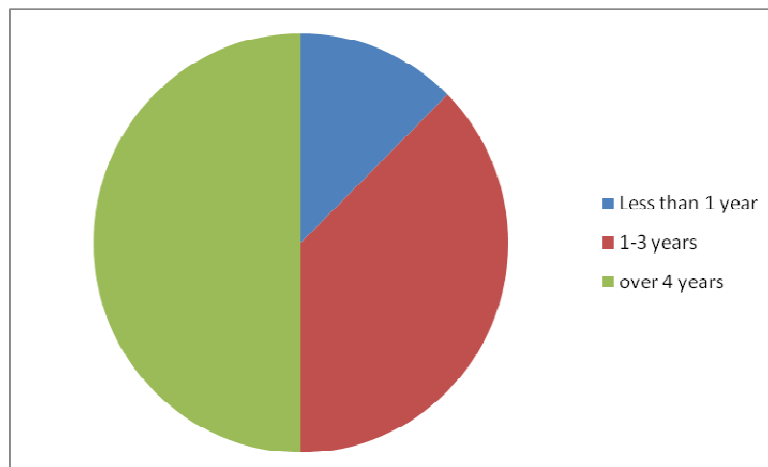
6. Results and Interpretation of Findings

We were able to successfully recruit eight participants to undertake the 'Being Mindful of the Carers project' which ran from February until June 2014 in Oban, Argyll. All the participants lived and cared for their relative/partner in their home. Only two of the participants had previously engaged with or had an awareness of mindfulness.

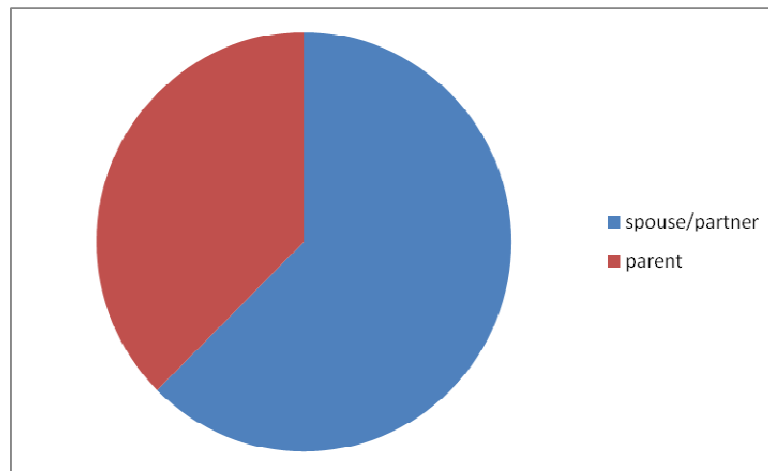
Gender of participants



Length of time as carer



Person cared for



Pre-Mindfulness Analysis

Upon analysis of the results and findings from the initial interviews of the eight participants we were interested in the effect of the caring role on their health, wellbeing, dignity and respect. There were specific themes evident within the analysis of the results, particularly around the areas of loss due to the caring role, the change within both marital and parental roles. Participants suggested that there were some significant changes in their relationship with their spouse and families as a result of undertaking caring responsibilities. For the carer the loss of the life that they used to have was significant, and many felt that they were now isolated and longed not only for the person but the life they used to have prior to the person with dementia becoming unwell. They also highlighted the lack of companionship from their spouse/parent. Another significant loss was someone to enjoy previous past times/conversations/outings and holidays. In particular also highlighted was the loss of physical touch/contact and sexual relationships between partners/spouse.

When asked about time for themselves they shared that they often felt like there was limited time for themselves now that they were caring for a relative/partner. There was a sharing of feelings that it was difficult to find some time for themselves and that this was often only very brief spells and often just undertaking ordinary everyday tasks such as taking a shower/bath as the only time they had to themselves. The pressure of time is significant even although at times the person with dementia attends day care/respite there was a

sense from some of the participants that they were always rushing back, time is precious and they feel under pressure and “snatching time” even when they have some free time. It is noted that not all participants feel the same pressure but this could be attributed to the abilities and capacity of the person they are caring for.

Relationships and the ability to make new friends also seemed to be difficult for the carers. While many of the participants mention that they have “old friends” and family members due to their caring responsibilities the ability to maintain and keep relationship/friendships going is more strained. Many participants reported that they don’t often invite friends back to their home now, and friends don’t often visit or at times avoid coming round due to the change in the relationships. There is also at times a difficulty in bonding with new people due to the change in their partner/relative. Interestingly many of the participants feel they have been able to make new relationships and friendships however this is largely due to their caring role and this tends to be people in similar positions, at the carers centre or through professional teams.

It was noted that many of the participants reported feelings of guilt and emotional isolation due their caring role. There is a sense in the participants that life is quite different now. There was discussion around the ability to exercise and undertake this which many of the participants felt it was difficult to undertake due to their role and demands as a carer. This often led to feelings of frustration in the carer. Some of the participants reported to feel down, “in a rut” at times and that the intensity of caring led to unpredictability, snapping and impatience over trivial matters. They also highlighted that life was “unpredictable” and at times they were concerned about losing control. It was noted that carer’s roles were often reversed and that this had led to sense of duty in undertaking the caring responsibility and the need to be financial, emotionally and physically available for the person with dementia.

It is noted that only one participant failed to complete the programme, leaving after week two due to lack of time to attend and carer commitments.

Post-Mindfulness Analysis

Seven participants attended and completed the programme, with the majority of the participants attending at least six or more of the weekly sessions. Citing difficulties for not attending as carer commitments, holidays, work or physical ill health. It is noticeable that a strong sense of support, community and new relationships were formed in the six month period. This was clearly evident through the weekly and further maintenance sessions. A sense of awareness and understanding of the difficulties encountered by each other was clearly evident. Most (but not all) of the participants found it quite easy to make time to attend the mindfulness training sessions however the ability to practice the techniques to the full extent of the programme was more challenging. It is noted that the carer's adapted their routines and care to allow mindfulness techniques to become part of their daily routine one way or another. The majority of the participants found mindfulness of great benefit, both personally and as carers. A few described it as a transforming experience. Only one participant found that mindfulness hadn't made much difference to them personally however they did notice some changes in their approach to caring for their person with dementia.

There were a wide variety of benefits reported by the participants. Most of the participants mentioned the basic ideas that underpin mindfulness – for example valuing the present moment and valuing self with more compassion. It was clear that they found mindfulness helped in their caring role. Particularly in those who have come to value themselves more, showing more kindness and respect of themselves. There was discussion around the ability to think more clearly and have “personal head space” now. Several of the participants found that they were more aware of their thoughts, and that they recognised that it was unhelpful to dwell on these, choosing to remain in the present moment with the aid of mindfulness practices. Generally there was a feeling in some of the participants that they felt better in themselves, they were able to cope better and felt less guilty about making time for themselves.

A very clear theme was that of a new found toleration to the situation they were in and to the behaviour of their cared for person. This was universally welcomed. It was recognised by the carers that there was no more time in the day however by employing a number of

simple strategies for example: getting up and going into another room, recognising that mood varies through the day; using the three minute breathing space this assisted them in their caring role. There was a generally calmer tone to the interviews at the end of the project, and there was no mention of loss or of what life had been like “before dementia”.

Some participants also recognised the effect of using mindfulness on their physical health and had noticed changes in their response to pain and their blood pressure. They all reported to have very much valued the support, friendship (and even love) and fellowship of the rest of the group. There was a feeling of genuine, mutual support. This bond was apparent in the sharing of experiences and mindfulness practices.

All participants described a variety of ways that they used, and continue to use mindfulness. Many cited the ‘three minute breathing space’ and the ‘body scan’ as their favourite practices and the most useful components of mindfulness. Many of the participants were already advocating the usefulness of mindfulness to others and most stated that they intended to continue with it and its benefits as a life-tool.

7. Discussion

It is celebrated amongst the project team and largely due to the commitment and determination of the team that the project was able to be delivered and completed as per the project plan. The project team all hold day jobs and clinical roles. It has to be noted that the members of the project team all had a role to play, from delivery, project management experience, lived experience, academic support and clinical supervision which has undoubtedly led to the completion and success of the project. The road to ethical approval was interesting however challenging, a huge amount of support and encouragement was provided not only by the ethics committee, but our research and development manager in support of the project and nurses who were new to the world of ethical approval and processes. Despite some early delays in gaining ethical approval, and on the second attempt successfully gained, the real work commenced! Getting to delivery was in effect the easy part.

In delivering the project we didn’t anticipate the intensity and sense of duty we would feel for the carers. At times the support for the carer was intense and as per our duty of care we were

“holding” not only the person with dementia but also the carer. Supervision was an integral component for the facilitators of the programme, to recognise the importance of caring for and being mindful of ourselves during the programme. This programme differed from other MBCT programmes as there is a focus on the carer and the person with dementia.

It is noted that there is a real sense of achievement in the project team in not only completing the project, and the relationships formed but the deeper understanding and awareness of how the caring role affects carers and their health, wellbeing, dignity and self-respect. Mindfulness has provided the carers with a tool to use and own themselves to support them in their role. The ability to maintain these relationships through the use of (MBCT) over the six month period definitely formed a sense of community amongst the group. Some lessons learned include the recognition of the time involved in applying, going through ethical approval, co-ordinating the delivery and maintaining the focus of the project, organising respite, maintaining financial balance and the completion of regular update reports whilst maintaining the day job is interesting and certainly challenging! Due to the remote and rural location of Argyll we had to centre our focus and delivery of the project within Oban and local areas, this maybe a factor to consider in the planning of future work.

8. Conclusion

The project successfully ran and completed on schedule despite delays in obtaining ethical approval. We were able to complete the programme in full as intended within our original aim. Providing this over a six month period facilitated a greater sense of community and relationships to develop with the participants. It was recognised by all the participants prior to the project that finding time for themselves was challenging, time was precious and their ability to seek time or space for themselves extremely challenging and at times felt difficult.

All the participants apart from one found that mindfulness has assisted them in their caring role. However it is recognised on completion of the programme that the participants now feel they don't have anymore time in the day but the manner in which they approach caring and previous challenges is different. While the structure of the mindfulness programme

over the eight week period held the group and provided the framework, this was challenging especially initially due to the emotion and coming together in the group.

However as the weeks passed the concept of mindfulness held the group this visibly changed. The continued support in the maintenance sessions provided that additional support and practice which the carers valued and continued to provide a focus around mindfulness for them. Practice for the carers was challenging however several of the participants reported to attempt to practice each week. They have however utilised and developed the use of the mindfulness tools to support them in their caring roles. A greater awareness and tolerance for their loved one has evolved with a greater awareness and respect for themselves. It is noted that several of the participants recognised a deeper sense of value in themselves and an awareness not only of their thoughts but in their value of themselves. Infact the thought of being kind to themselves is critical in this role showing a deeper awareness and insight of themselves.

While we recognise the limitations to this study we do feel that the results have proved interesting and that it would be worthwhile to repeat a similar study potentially as a longitudinal study. We propose that this approach which maybe suitable for other carers in their roles or indeed with the carer and the person with dementia shortly after diagnosis.

There were several benefits to the participants in participating in this research project, which included:

- a) The potential to provide carers with an increased awareness of the effect of caring upon their health and well being and the importance of caring for themselves.
- b) Inclusion in wider society.
- c) Provision of respite care.
- d) Development of alternative coping mechanisms within their caring role, and to promote their health and well being.

9. Recommendations

- For practitioners to consider the role of the carer in every day practice and the effect of this role on not only the carer's but the person being cared for health and wellbeing.
- To recognise the benefits of integrated team working as an individual and the advantages to supporting care in this manner.
- To source or train further mindfulness trainers within the NHS/Local Authority or Third Sector.
- To deliver and repeat further mindfulness based cognitive therapy programmes to carers across Argyll and Bute.
- To give consideration to the potential challenges in delivering such a programme across the diverse geography of Argyll and Bute.
- Mindfulness practitioners to continue to use supervision to support themselves in this process.
- To consider this process and apply to run further research projects potentially within a longitudinal study would be of benefit.

10. Impacts of the Project

The project has been impactful for a number of reasons. The process of project management, leading and completing the project has been not only challenging but hugely rewarding for the project lead and the team. The ability to develop and establish relationships with the participants is not only humbling but their warmth and acceptance of this approach and acceptance of the unknown has been potentially life-changing for the majority of the participants but members of the project team also. The increased awareness of daily challenges, pressures and the application of mindfulness has supported changes in the project teams work practices and approaches. The opportunity to undertake the project, and the skills developed in the team around research and leadership is clearly visible and apparent leaving many of us with skills we didn't know we had!

Finally I would like to extend my thanks to The Burdett Trust and The Queens Nursing Institute for Scotland for supporting and funding this project in the first instance. NHS Highland and The West of Scotland Research and Ethics Committee for their support, vision and belief in this project. Wendy, Ylva, Diane, Pat, Andy as the project team for their deep determination and support to complete the project despite the odds and the day jobs! Alistair and Ishbel for their support and supervision.

But finally massive thanks to the participants who without we would not have gained such an insight into the caring role and the effect of mindfulness upon this...

Thank You!

11. Dissemination Plan

- Submit report and share results with funders - QNIS/Burdett Trust
- Provide report to participants and fellow carer organisations
- Provide Internal Report for Line Managers/Interested Colleagues
- Share report with Reshaping Care for Older People work stream within NHS and Stakeholders
- Share findings via various appropriate mediums - Social Media etc.
- Submit abstracts for future conference presentations
- Submission and hopeful publication within peer reviewed journals
- Poster presentation accepted at European Alzheimer's Conference, October 2014

12. Future developments/ next steps

- Provision of continued support for participants through The Community Dementia Team and the Dementia Resource Centre.
- Continued monthly mindfulness sessions in Dementia Resource Centre for participants.
- Share findings and results with NHS/Stakeholders and Carer Organisations.

- In sharing the results of the project with a view to influence change and/or the potential to run further programmes within Community Dementia Teams across the localities.
- To enquire for additional funding to support respite care for carers of people with dementia to facilitate attendance at future groups.

13. References

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14. Financial Report

	£
Staffing (delivery of the programme and provision of respite care)	6,035
Sundries	1,115
Printing Final Report	150
Posters	200
Total Cost	7,500

Appendices:

Appendix 1 – Carer Information Leaflet

Appendix 2 – Carer Consent Form

Appendix 3 – West of Scotland Research and Ethics Committee Approval Letter

What are the side effects when taking part?

There are no known side effects, although it is important to recognise that you may experience heightened emotions during the programme, and ongoing support is available.

What are the possible disadvantages and risks of taking part?

We are not aware of any disadvantages or risks of taking part.

What are the possible benefits of taking part?

We would hope that by undertaking this programme it would have an effect upon your health and wellbeing therefore supporting you within your caring role. Participating in this study may identify both benefits and drawbacks to the use of mindfulness based cognitive therapy in enhancing support for carers of older adults with dementia, which will be shared widely across Scotland.

What happens when the research study stops?

The mindfulness programme will equip you with the skills to look after your health and well-being more effectively and if any issues arise then follow up will be arranged with the appropriate health care professional. On going support is available at local carer support groups.

What if something goes wrong?

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS Scotland complaints mechanisms should be available to you. We would encourage you to contact one of the team members.

Will my taking part in this study be kept confidential?

All information collected from you during the course of the research will be kept strictly confidential. Each participant is

allocated a number. Any information about you which leaves NHS locations will have your name and address removed so that you cannot be recognised from it. It is our duty of care to inform your GP/relevant other professional if any issues/concerns arise for either yourself or the person that you care for, during the study.

What will happen to the results of the research study?

The results will be published in a report to the Queen’s Nursing Institute Scotland, (QNIS) registered charity SC005751. This will be published on their website www.qnis.org.uk. You will be sent a copy if you so wish. The project team are to present the results at a national celebration/dissemination event in 2015. Publication may be in a number of journals nationally.

Who is organising and funding the research?

QNIS are funding the research and a contract has been signed with NHS Highland.

Who has reviewed the study?

West of Scotland Research and Ethics Committee, NHS Highland Research and Development Team, have reviewed and approved the study.

Contact for Further Information

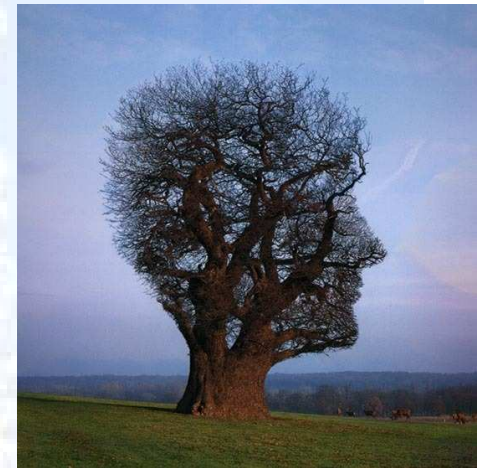
Gillian Davies, Project Lead

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Being Mindful of the Carers



Carer Information Leaflet

November 8th 2013

www.qnis.org.uk/funding/delivering-dignity/

Invitation

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part. Thank you for reading this.

What is the purpose of the Study? Our aim is to pilot a Mindfulness Based Cognitive Therapy (MBCT) group programme over a six month period to carers of people with dementia within the local community of Oban, Argyllshire.

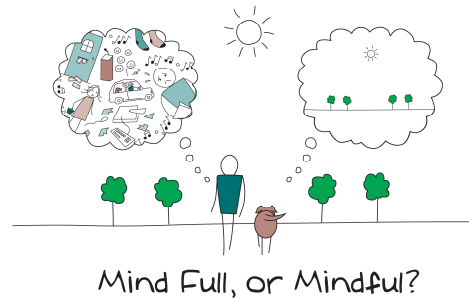
“Mindfulness is both a skill and a way of living. It is about living in the here and now rather than being caught in the past or worrying all the time about the future.” (Mindfulness Scotland, 2013).

The project will explore and understand the effect of mindfulness based cognitive therapy upon the health and wellbeing, dignity and self-respect of carers for people with dementia in a remote and rural setting.

Why have I been invited to take part? You have been invited as a carer of a person with dementia to undertake participation in a group mindfulness programme, to provide you as a carer with –

- An increased awareness of the effect of caring upon your health and well-being
- An increased awareness of the importance of caring for yourself
- An increased awareness of the effect of stress
- To lead to improvements in your self-respect and dignity.

Do I have to take part No, it is up to you to decide whether to take part.



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What will happen to me if I take part ? We will complete a consent form with you prior to undertaking the study. You will be asked to undertake an interview prior to the delivery of the mindfulness programme, and again after 6 months. This is to identify your understanding of the role as a carer on your health and wellbeing and to evaluate the effectiveness of the mindfulness programme. The programme will be delivered locally to 8 carers of people with dementia over a 6 month period. The initial programme will be run weekly for 8 weeks. (2 hour session) Mindfulness training also involves home practice up to one hour a day and involves tasks such as listening to tapes, and performing brief exercises, for 6 out of 7 days. To help you find the room in your life for this new commitment it is helpful to consider the following:

: Where in your day will you find the time for needed practice?

: Let others in your family or social circle know what is involved

: treat yourself with kindness throughout this time, especially if you run into some rough spots

Follow up support will then be sought from existing health and wellbeing carer networks. You will be free to withdraw at any time without giving a reason. This will not affect the standard of any future care received.

Your GP will be informed of your participation in the study.

Carer Commitments? We will be able to provide some support for respite to enable you to attend the programme.

What is the procedure that is being tested? The Mindfulness based cognitive therapy programme encourages carers to focus upon the present moment without judgement, and showing kindness to themselves. It is a technique recognised by the National Institute of Clinical Excellence (NICE). Further information can be found at www.mindfulnet.org

What are the alternatives? Health and wellbeing may be achieved through regular exercise or inclusion in social activities, and/or carer support groups.

Centre Number: NHS Highland
 Study Number: 946
 QNIS Number: ENMTC01
 Participant Identification Number for this research study: -

Being Mindful of the Carers

CONSENT FORM

Name of Researchers: Gillian Davies, Wendy O’Ryan, Dr Diane Fotheringham, Ylva Champion

Please initial box

1. I confirm that I have read and understand the carer information leaflet version 2 dated November 8th 2013 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I agree to my GP, Dr(insert name of GP) being informed of my participation in the study, and for my GP or other professional to be contacted should any issues/concerns arise for either myself or the person with dementia that I care for.
4. I understand that the interviews will be audio recorded and that any quotes used will be anonymised.
5. I would like a copy of the final report.
6. I agree to take part in the above study.

Name of Participant

Date

Signature

Name of Person taking consent
(if different from researcher)

Date

Signature

Researcher

Date

Signature

West of Scotland REC 3
Ground Floor – The Tennent Institute
Western Infirmary
38 Church Street
Glasgow G11 6NT
www.nhsggc.org.uk

Mrs Gillian Davies
Community Mental Health Nurse
NHS Highland
Willowview
Oban
PA34 4SB

Date 13th December 2013
Your Ref
Our Ref
Direct line 0141 211 2123
Fax 0141 211 1847
E-mail Liz.Jamieson@ggc.scot.nhs.uk

Dear Mrs Davies

Study title:	Being Mindful of the Carers
REC reference:	13/WS/0280
IRAS project ID:	140320

Thank you for your letter of 15 November 2013 and further email correspondence responding to the Committee's request for further information on the above research and submitting revised documentation and submitting revised documentation.

The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Mrs Liz Jamieson, Liz.Jamieson@ggc.scot.nhs.uk.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		01 October 2013
Covering Letter		15 November 2013

Interview Schedules/Topic Guides - Initial	2	27 November 2013
Interview Schedules/Topic Guides - final	2	27 November 2013
Investigator CV		05 July 2013
Letter of invitation to participant	3	27 November 2013
Other: Unfavourable Opinion Letter		29 August 2013
Other: Contractual Agreement QNIS		25 June 2013
Participant Consent Form	3	08 November 2013
Participant Information Sheet	2	08 November 2013
Protocol	1	25 February 2013
REC application		08 October 2013
Response to Request for Further Information		15 November 2013

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

13/WS/0280

Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

West of Scotland REC 3

Sub-Committee of the REC held in correspondence

Committee Members involved in the Review:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Angus McFadyen	Reader in Health Statistics	Yes	
Mrs Monica Dickson	Retired - Lay Plus Member	Yes	
Mr Eoin MacGillivray	Retired Dentist - Vice Chair	Yes	
Dr Paul Mattison	Consultant Physician in Rehabilitation Medicine	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Liz Jamieson	Committee Co-ordinator