ABSTRACT

Background This paper describes the development of a complex intervention to promote mental wellbeing using the revised framework for developing and evaluating complex interventions produced by the UK Medical Research Council (UKMRC).

Methods Application of the first two phases of the framework is described—development and feasibility and piloting. The theoretical case and evidence base were examined analytically to explicate the theoretical and empirical foundations of the intervention. These findings informed the design of a 12-week mental wellbeing promotion programme providing early intervention for people showing signs of mental health difficulties. The programme is based on the theoretical constructs of self-efficacy, self-esteem, purpose in life, resilience and social support and comprises 10 steps. A mixed methods approach was used to conduct a feasibility study with community and voluntary sector service users and in primary care.

Results A significant increase in mental wellbeing was observed following participation in the intervention. Qualitative data corroborated this finding and suggested that the intervention was feasible to deliver and acceptable to participants, facilitators and health professionals.

Conclusions The revised UKMRC framework can be successfully applied to the development of public health interventions.

Keywords mental health, public health

Introduction

Mental ill health is a considerable global public health burden, with major personal, societal and economical consequences. Local, national and international policies highlight the need for mental health promotion and early intervention strategies aimed at the reduction of this burden. The research-based case for effective early identification and treatment is strong given the wide-ranging costs of mental ill-health that are spread over many years and the corresponding benefits of positive mental health. This research involved the development of a complex intervention which aims to promote mental wellbeing and provide early intervention for people showing signs of sub-threshold mental health difficulties. The paper describes how the approach suggested by the UK Medical Research Council (UKMRC) can be applied to mental health promotion and the development of public health interventions.

Design and methods

We used a development approach consistent with the revised framework recommended for developing and evaluating complex interventions proposed by the UKMRC. This framework states that an intervention may be considered to be complex if a number of interactive components and outcomes are present, if it targets multiple behaviours and if it affords a degree of flexibility. There are four iterative phases though these phases need not necessarily follow a linear or cyclical sequence. Phase 1, development, involves identifying and appraising the evidence base, identifying and applying theory to the development of an intervention and modelling intervention processes and outcomes. Phase 2, feasibility and
Identifying and appraising the evidence base

The MRC framework emphasizes the necessity to identify supporting research literature and use practical professional experience for the development of an intervention. Supporting evidence included research that identified 10 positive steps for mental health—accepting who you are, talking about it, keeping in touch with friends, getting involved, keeping active, drinking in moderation, learning new skills, doing something creative, relaxing and asking for help. These steps were later reiterated by the National Institute for Mental Health in England as having the potential to protect and improve mental wellbeing. Available interventions largely consisted of the provision of information and/or advice and were not based on a theory-based interactive approach.

Medline, Cochrane and PsychINFO were searched for interventions which used one or more of the 10 positive steps to promote mental wellbeing. No published studies were found which had used the 10 positive steps collectively in an intervention. Evidence was found for the effectiveness of each positive step on an individual basis (see Table 1). Friedli et al. reviewed available evidence regarding the use of the individual positive steps for mental health promotion. There was variation in the quality and quantity of studies about the constructs or areas covered by the individual steps. For example, experimental research investigated the mental health benefits of exercise, whereas the area of creativity has been investigated only in terms of post hoc opinion surveys of participants. Overall, there was fairly good evidence to support the use of positive step messages as the basis of an intervention designed to promote positive mental health, prevent mental health problems and to improve the quality of life of people living with mental health difficulties.

Developing the theoretical structure of the intervention

The MRC framework recommends the examination of theoretical perspectives that may explain the effectiveness of the intervention. The individual areas covered by the 10 positive steps were mapped onto theoretical constructs from psychosocial and behaviour change theories. This link into the theory surrounding each positive step further strengthened the rationale for the intervention. Also, the iterative process considered the potential relationships between the steps as well as techniques for effecting change and for inclusion in the intervention. This analysis signposted the research team to appropriate intervention content. The 10 positive steps mapped onto 5 theoretical constructs of self-efficacy, self-esteem, purpose in life, resilience and social support. Mental health promotion interventions tend to aim to have the dual effects of reducing problems and increasing competencies and, so, steps relating to coping with anxiety and depression were included.

The construct of self-efficacy is a core component of Bandura’s socio-cognitive theory of behaviour change. According to Bandura’s theory, self-efficacy refers to the
<table>
<thead>
<tr>
<th>Step name and aim</th>
<th>Summary of evidence</th>
<th>Target theoretical constructs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1—Creativity: to encourage people to explore their creative side and understand how being creative is good for mental wellbeing</td>
<td>Strengthening opportunities for creativity has a protective effect on mental health. A growing number of studies suggest that creative activity benefits positive mental health, by, for example, developing self-esteem and increasing social contact and/or providing a sense of purpose and meaning.</td>
<td>Self-efficacy, Self-esteem, Social support, Anxiety, Mental wellbeing</td>
</tr>
<tr>
<td>Step 2—Accept who you are: to help people see how valuing themselves and others and accepting who they are is good for mental wellbeing</td>
<td>Valuing yourself and others is associated with improved wellbeing. Evidence links low self-esteem with the onset of depression, suicidal behaviour and eating disorders.</td>
<td>Resilience, Self-esteem, Mental wellbeing</td>
</tr>
<tr>
<td>Step 3—Get talking: to help people see and experience the benefits of talking and the impact this can have on improving mental wellbeing</td>
<td>There is good review level evidence that ‘talking therapies’ are effective in people with mental health difficulties. Evidence that talking protects mental health in non-clinical populations is limited and so more research is required in this area.</td>
<td>Self-esteem, Social support, Mental wellbeing</td>
</tr>
<tr>
<td>Step 4—Get involved: to encourage people to get involved in activities and organizations and help them understand how getting involved is good for mental health.</td>
<td>Getting involved in activities and feeling that you are making a contribution has showed positive benefits for quality of life and mental wellbeing. However, more research is needed as findings are mixed and much of the research has focused on older people.</td>
<td>Self-esteem, Resilience, Social support, Depression, Mental wellbeing</td>
</tr>
<tr>
<td>Step 5—Health and wellbeing: to understand the links between physical health and mental wellbeing and show how to promote and protect physical and mental wellbeing</td>
<td>Good mental health is linked to good physical health. For example, depression increases the risk of heart disease 4-fold (even when other risks like smoking are controlled). Depression also impacts on the health outcomes of chronic illnesses such as stroke, diabetes, asthma and arthritis. Interventions designed to promote physical health might tend to improve mental health and vice versa.</td>
<td>Physical health, Mental wellbeing</td>
</tr>
<tr>
<td>Step 6—Try something new: to encourage trying something new and to recognize that trying new things can be a positive experience</td>
<td>Lifelong learning is associated with a range of mental health benefits; however, more research in this area is required.</td>
<td>Self-efficacy, Purpose in life, Social support, Anxiety, Depression, Mental wellbeing</td>
</tr>
<tr>
<td>Step 7—Ask for help: to encourage asking for help more readily and explore why asking for help is a strength not a weakness</td>
<td>Asking for help may have potential benefits for mental health though further research is required.</td>
<td>Resilience, Purpose in life, Social support, Mental wellbeing</td>
</tr>
<tr>
<td>Step 8—Keep active: to encourage participation in physical activities and show how keeping active is good for mental wellbeing</td>
<td>There is a positive association between physical activity, exercise and mental wellbeing. Physical activity may help to prevent the onset of mental health difficulties and to improve the mental wellbeing of the general public. Barry et al. found that people with higher levels of positive mental health were more likely to report better health, be physically active and less likely to smoke. Regular physical activity is associated with lower rates of depression and anxiety and a greater sense of wellbeing.</td>
<td>Self-efficacy, Purpose in life, Social support, Anxiety, Depression, Physical health, Mental wellbeing</td>
</tr>
</tbody>
</table>

Continued
extent to which a person believes that they have the ability to perform a task or manage a situation. This ‘can do’ cognition reflects the belief of being able to control challenging demands by taking adaptive action. It has been shown to be a universal construct in 25 nations. Self-efficacy is a protective factor that may enhance motivation and lead to effective problem solving, followed by an increase in positive emotions. A low sense of self-efficacy is associated with negative emotions and helplessness including anxiety and depression. The growth of self-efficacy continues through life as new skills, experiences and understanding are acquired.

Self-esteem may be a major component in positive mental health and act as a protective factor or buffer against the impact of negative influences. Self-evaluation influences personal aspirations, goals and interactions with others. Positive self-esteem has been found to have beneficial outcomes in terms of physical and mental health while conversely low self-esteem is a risk factor for depression, suicidal thoughts and eating disorders. Orth et al. found low self-esteem to be a risk factor for depression at all phases of the adult life span. The concept of global self-esteem is defined as one’s overall sense of worthiness as a person, a person’s positive or negative attitude towards themselves.

Beliefs that give one the feeling that there is purpose in and meaning to life are an important dimension of psychological wellbeing. Zika and Chamberlain have found strong relationships between meaning in life and psychological wellbeing. Other studies have linked meaning in life with positive affect and life satisfaction.

Social support refers to the ‘perceived comfort, caring, esteem or help a person receives from other people or groups’. Social support tends to be assessed in terms of the number of friends ‘supplying’ social support—the social network and the satisfaction with this support. Strengthening opportunities for social support has a protective effect on mental health. Higher levels of social support have been associated with positive mental health and poor levels of social support with higher levels of psychological distress. Increased social support has also been linked to a decreased stress response and a subsequent reduction in physical illness.

Resilience refers to positive adaptation and development in the face of adversity. The study of resilience has grown from observations that some children function competently despite noticeable risks and adverse conditions. Resilient people regard negative events as less stressful and bounce back from the adversities of life. This ‘bouncing back’ can mean a return to a previous level of functioning or simply not showing negative effects from the experience. Resilient people use their experience to build strengths so that they can grow as a person and cope with stresses and challenges in the future. A range of cognitive, social and environmental resources can help to boost the resilience of people, even when living in difficult circumstances. These resources can help promote their health and protect them against illness and other negative outcomes. They include a positive attitude (leading to positive, health-related behaviours) and relationships of trust and reciprocity built up through, for example, friendship, family and faith networks.

The theoretical constructs collectively point to a higher order construct of mental wellbeing. The skills and attributes associated with mental wellbeing may lead to improved physical health, better quality of life, reduced crime, higher educational attainment, economic wellbeing and personal dignity. Mental wellbeing may also increase the capacity of the individual to exercise choice and control over their lives. Mental health and wellbeing can be considered to encompass the following aspects: emotional (affect/feeling), psychological (positive functioning), social (relations with others) and spiritual (sense of purpose in life).
Modelling process and outcome

The evidence base and theoretical findings informed the design of an intervention entitled the ‘Positive Steps Programme’ (PSP). This is a 12-week group-based programme for people experiencing situational problems (e.g. relationship breakup, unemployment, financial crises) and present with sub-threshold mental health difficulties (e.g. low-level anxiety, low mood, poor coping, low self-esteem). The programme is delivered by pairs of trained facilitators working from a detailed procedure manual. Each session is designed to last for 2 h. The intervention is designed to raise awareness and knowledge about how to protect mental health and wellbeing and to increase skills and personal resources that will enable choices and lifestyle changes that promote mental wellbeing. A participant workbook summarizes each positive step and encourages participants to record their thoughts and to set goals from each session. The intervention is designed to have a degree of flexibility regarding the activities that are scheduled to take place during each step. Whilst each step is covered, the content or activities of the step may vary slightly according to the resources available, the skills of the facilitator, the length of the sessions and the age/gender of the particular group. Each step outlines the aim of the session, the provision of background information for the session, discussion of the topic addressed by the session, participating in activities and evaluation of the session. During the first session, participants introduce themselves and future sessions and activities are planned. Participants receive a list of websites and resources which they may use to explore the 10 steps and they are encouraged to explore and engage in local activities and opportunities.

Describing the core components of an intervention helps to communicate the effective aspects and increase the likelihood that it is replicable. Also, it is important to specify the reason why a given action in an intervention is expected to have a particular outcome. In order to address these issues the intervention was described in terms of behavioural change techniques (see Table 2). A central premise of positive steps is that strengthening protective factors will enhance the ability to function well emotionally, psychologically, socially and spiritually (sense of purpose in life) and that this enhancement will mitigate the effects of negative life events and encourage the performance of mental health and wellbeing promoting behaviours. In order to aid the UKMRC framework modelling process, a logic model was developed (see Table 3) using published guidelines. Logic modelling involves developing a diagrammatic plan that links programme inputs, resources and activities to programme objectives and outcomes; and in the case presented here, the logic model helped to explicate and connect the various aspects of the underlying theory about wellbeing and its promotion.

Assessing feasibility and piloting methods

As recommended by the MRC framework, pilot studies were conducted to test the feasibility of the intervention, pilot procedures and to assess the acceptability of the intervention. A mixed methods approach was used to test the feasibility of the delivery of the intervention in different settings and progressively refine the design and procedures. In the first study
### Table 3 Intervention logic model

<table>
<thead>
<tr>
<th>Inputs/resources</th>
<th>Activities</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What is invested</strong></td>
<td><strong>What is done</strong></td>
<td><strong>Who is reached</strong></td>
</tr>
<tr>
<td>Staff (project team)</td>
<td>Conduct meetings</td>
<td>Intervention participants</td>
</tr>
<tr>
<td>Time</td>
<td>Develop intervention content and resources</td>
<td>Facilitators</td>
</tr>
<tr>
<td>Money</td>
<td>Develop manual</td>
<td>Community and voluntary organizations</td>
</tr>
<tr>
<td>Research evidence</td>
<td>Agree inclusion and exclusion criteria</td>
<td>Primary care</td>
</tr>
<tr>
<td>Materials</td>
<td></td>
<td>Project staff</td>
</tr>
<tr>
<td>Partnerships</td>
<td>Agree referral process</td>
<td>Other HSC Trust staff</td>
</tr>
<tr>
<td>Delivery locations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Project management team</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research team</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assumptions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Necessary partnerships can be created</td>
<td>Time and resources are available</td>
<td></td>
</tr>
</tbody>
</table>

**External factors**

- External stress, bereavement or other adverse life events for individual participant
7 facilitators delivered 13 PSP programmes to a total of 109 participants in community and voluntary group settings. Acceptability of the intervention to participants and health professionals was assessed using open-ended questionnaires and a focus group with seven key informants (three programme developers, the project advisor and three facilitators). Feedback suggested that the intervention was well accepted by participants and facilitators. The intervention was delivered successfully to a variety of age ranges and participant groups (for example youth projects, a neighbourhood renewal project, mixed age community groups and a group of older people). Feedback was used to amend and improve the intervention before the second study. For example, programme structure was refined, an introductory session added and the need for advance preparation by facilitators highlighted. A delivery flowchart, clearer description of questionnaire completion and a requirement for two facilitators to deliver the intervention were added to the manual.

The Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) was used to measure mental wellbeing. The WEMWBS is a relatively new measure which assesses mental wellbeing on a 14-item 5-point Likert scale and covers both hedonic and eudaimonic aspects of mental wellbeing including positive affect (feelings of optimism, cheerfulness, relaxation) satisfying interpersonal relationships and positive functioning (energy, clear thinking, self-acceptance, personal development, competence and autonomy). The range of scores for WEMWBS is 14–70, with higher scores representing a higher level of mental wellbeing. WEMWBS was developed by an expert panel and validated on a student and representative population sample. Other researchers have validated the WEMWBS. The WEMWBS tends to avoid the ceiling effects displayed by other scales by focusing on positive mental health and has a near normal distribution. A secondary analysis of 12 different intervention studies that used WEMWBS as an outcome measure found the measure to be responsive to change at both the individual and group levels and in both general and psychiatric populations.

In the developmental evaluation presented here, 49 WEMWBS ‘before-and-after’ questionnaires were completed in intervention programmes delivered in community and voluntary settings. The mean score difference on the WEMWBS showed an improvement of 5.61 points from baseline to exit (SD = 11.66). An indicative paired samples t-test found a statistically significant difference between the mean scores at baseline (M = 40.98, SD = 12.35) and exit (M = 46.02, SD = 10.07); t(48) = −3.05, P = 0.004). Although 109 participants availed of the 13 intervention programmes, only 49 completed sets of WEMWBS questionnaires. Facilitator feedback questionnaires and focus group data highlighted the need for more emphasis to be placed on the importance of completion of the WEMWBS and so clearer instructions on how to complete the WEMWBS were added to the intervention manual in response to these comments.

The second study involved the delivery of one intervention programme to six participants in a primary care setting. The WEMWBS was again used to measure mental wellbeing in addition to a one-item global rating of change in mental wellbeing score on a 10-point scale as recommended by Maheswaran. Although due to small referral numbers the number of primary care participants was too low to enable statistical analysis, data showed an improvement of 6 points on the WEMWBS, comparable with the finding in community and voluntary groups. Five participants completed the one-item global rating of change and three described their mental wellbeing as ‘quite a bit better’ and two as ‘a little bit better’. The second part of the developmental evaluation focused more in depth on process evaluation—brief interviews were conducted with five intervention participants and six project personnel (e.g. health development, coordinator, manager), four participants and two facilitators completed feedback questionnaires and the researcher undertook documentary analysis and observational visits. Qualitative data indicated that participants, facilitators and key informants held positive views. Particular benefits that were noted included improved mental wellbeing and confidence and social contact opportunities and participants rated the content and practical aspects of programme delivery highly. The individual step sessions were rated as being either very useful or useful. A referral process via primary care to the intervention was difficult to implement with lower than expected referral rates and difficult-to-engage general practitioners. Suggestions regarding general practitioner involvement and an improved referral process included a dedicated referrals facilitator and/or the installation of a prompt on the computer screen of general practitioners during consultation and the delivery of information to participants perhaps in the format of a website or DVD.

**Discussion**

**Main finding of this study**

This paper describes the initial development and testing of an intervention aimed at promoting mental wellbeing and describes how the approach suggested by the UKMRC can be applied to the development of public mental wellbeing interventions. In particular, the flexible and iterative nature of the MRC guidelines enabled an intervention to be developed.
based on 10 existing positive steps for mental wellbeing, with a supporting theoretical rationale and evidence base.

**What is already known on this topic?**
The review of the research literature indicated support for the effectiveness of each individual positive step or construct particularly with respect to their potential to improve mental health. However, evidence was sparse regarding the use of the steps collectively or in an integrated way as a structured programme targeted at promoting and improving mental wellbeing. Interventions that are derived from and based upon theory have been shown to be more effective than interventions without an explicated theory (see ref. 68, for example). However, few studies have published details about how wellbeing interventions were developed and details about the theoretical basis of interventions were lacking.

**What this study adds**
This evaluation provides an example of how the MRC framework can be applied to the development and testing of public mental wellbeing interventions. Careful attention to the theoretical foundations of the intervention helped to clarify how the different elements may contribute to positive outcomes. The review of relevant studies indicated that each targeted theoretical construct may play a significant role in terms of contributing to mental wellbeing. Collectively, the individual constructs point to a potential explanatory framework and possibly to a higher order construct of mental wellbeing. Further research is required to identify the links between postulated theoretical mechanisms, behaviour change techniques and outcomes generally as well as in the specific case of this intervention. Specific areas or steps that would benefit from more research include talking, asking for help, relaxation and creativity. The review and analysis did not uncover any studies that examined the positive steps as a package, or linkages between the steps of the intervention. Whilst there is a lack of evidence about these issues, the results of this feasibility work along with available research relating to the individual constructs, intervention ingredients and outcomes suggest that the intervention shows potential to be effective in terms of promoting mental wellbeing. It appears that the increase in mental wellbeing that was observed after participating in the intervention may be significant. Qualitative data corroborated this finding and suggested that the intervention was feasible to deliver and acceptable to participants, facilitators and health professionals.

**Limitations of this study**
A small sample size was observed in the developmental testing and evaluation of the intervention in the primary care setting. The poor uptake in primary care points to the need for further developmental work and feasibility testing before recommending implementation of the intervention. In contrast, the organization, provision and delivery of the programme in community settings appeared to occur with relatively little difficulty. Further refinement of design and procedures and more research with a larger sample is required. Specifically, an appropriately powered randomized controlled trial would enable completion of Phases 3 and 4 of the UKMRC framework and assess the effectiveness of the intervention.

**Acknowledgements**
The authors thank Fiona Molloy and Alison Doake from the Health Development Team (SEHSCT) for the development and implementation of the intervention; and Jason White (Assistant Director, SEHSCT) for his support and management of the Steering Group. We are grateful to Paul Carlin (SEHSCT) for his advice and support regarding Trust R&D requirements and the general conduct of the research. Thanks to the Public Health Agency for funding the evaluation and for the support of Chris Totten, Mabel Scullion and Danielle Sinclair. Finally, we are very grateful to the individuals who participated in, or facilitated, the intervention and the pilot evaluation.

**Funding**
This work was supported by the HSC Public Health Agency.

**References**


