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What is This?
A community pain service solution-focused pain management programme: delivery and preliminary outcome data

Rebecca Simm, Joanne Iddon and Chris Barker

Summary points:
1. This article introduces a rationale for a solution-focused approach to a community-based pain management programme (PMP), describing delivery and preliminary outcome data.
2. It suggests PMPs can be feasibly run in the community without necessity for hospital care setting.
3. A community setting is also advantageous in that it allows maintenance of social networks and close third-sector links to support long-term, sustained mental well-being.
4. Solution-focused psychological approaches help the clinician tap into patient expertise and develop rich descriptions of the patient’s preferred future, enhancing self-efficacy and empowerment.
5. Evaluation found significant statistical and clinical improvements in pre–post pain self-efficacy, mental well-being and function (but findings were limited by internal and external validity and no significant effect was found on pain levels).
6. Statistically significant change was maintained at 10 weeks for self-efficacy and function (and for the latter, clinically significant change was also maintained); improvements in mental well-being showed maintenance at all measured time points (up to 12 months) in terms of both statistical and clinical significant changes.

Keywords
Pain management programme, solution focused, community pain management, pain self-efficacy, well-being, chronic pain, function

Introduction

This article aims to (a) present a brief overview of psychological approaches to pain management programmes (PMPs), introducing a rationale for using a solution-focused (SF) approach in chronic pain; (b) describe a PMP delivered using a SF approach in a community setting; and (c) report preliminary PMP evaluation data. We aim to report on outcomes from ‘real-world’ practice and describe the delivery of a combination of principles we believe to be important when working in the National Health Service (NHS) with people with chronic pain.

Brief overview of psychological approaches to PMPs

PMPs are usually founded on ‘deficit-based’ models of psychological intervention, mainly using principles from cognitive behavioural therapy (CBT) where the clinician provides guidance and advice and the aim is to teach patients cognitive and behavioural pain coping strategies. Many outcome studies have been reported using CBT approaches in chronic pain and, citing a recent Cochrane review, CBT is generally held to be a ‘useful approach to the management of chronic pain’.1 The Cochrane reviewers also describe some limitations of the approach, finding that CBT had small positive effects on disability and catastrophising,
but not on pain or mood, when compared with active controls. CBT had small to moderate effects on pain, disability, mood and catastrophising immediately post-treatment when compared with treatment as usual/waiting list, but all except a small effect on mood had disappeared at follow-up. There is also a growing evidence base for the use of ‘third-wave’ CBT approaches in chronic pain (and their use on PMPs), for example, acceptance and commitment therapy (ACT), which promote acceptance, resilience and personal values. There is evidence that PMP outcome improvements consistently track with increases in processes such as acceptance of pain, values-based action and psychological flexibility.\(^2\) Traditionally, PMPs have been hospital based and provide short-term intervention in people’s lives (sometimes quite some way from their homes), with limited opportunity to form support communities.

In the recent White Paper on Health, *Equity and Excellence: Liberating the NHS*,\(^3\) the coalition government is continuing the policy direction from the Labour government’s ‘NHS Plan’ of 2002 in facilitating patients to self-care, encouraging shared decision-making and empowering patients. The 2008 Chief Medical Officer’s report\(^4\) (which dedicated a section to pain management) described that ‘patients report that being listened to and given choices over treatment are just as important as the therapies themselves’ and ‘care for long-term conditions such as complex and chronic pain should be focused on the patient’. Over a decade ago now, the Department of Health (DoH) outlined an expert patient strategy,\(^5\) proposing that ‘knowledge and experience held by patients has been for too long an untapped resource’.

An alternative psychological approach, currently experiencing a growth in clinical interest and research in many fields, is solution-focused brief therapy (SFBT). SF approaches are non-directive and client-led; they assume that clients have the resources to deal with their difficulties and that small steps can change a vicious cycle of problem maintenance to problem resolution.\(^6\) SFBT aims to bring about change through concentrating on client’s preferred futures and instances of success in the past and present.\(^7\) It focuses on achievable goals and can be easily learned and practised by all health professionals.\(^8\) SF techniques include inviting problem-free talk, eliciting detailed descriptions of the patient’s goals and noticing and complimenting the patient on their existing strengths and abilities. A further technique as that of 0–10 scaling, where the ‘best hope’ is clearly detailed (e.g. ‘living well despite pain’) and positioned at 10 (in stark contrast to most pain scales where 10 is usually framed in terms of ‘the worst pain possible’). The patient is invited to rate their position in terms of their best hopes, notice what is helping and tentatively invited to consider ‘just suppose you get one point higher – what will be different?’ This method ‘frees up’ thinking, so that solutions become a more creative top-down process, rather than being limited by only re-defining the problem. Working towards meaningful patient-led hopes or outcomes is clearly important; however, Beale et al.\(^9\) found that in studies focusing on outcome choice for psychological treatment of chronic pain, only 2 outcomes (physical activities and emotional well-being) out of 19 domains were assigned comparable importance by survey respondents and clinician–researchers.

The clinician’s stance in SFBT is that of an ‘expert by invitation’, sharing clinical expertise with the patient to build towards their preferred future *where invited*. In a paper outlining the use of the SF approach in relation to measuring and working with pain, Bray (2013, personal communication) suggests that ‘the SF model admits of all possibilities in terms how pain is construed, measured and remedied, patients being seen as connoisseurs, professionals as being experts by commission (rather than assumption), and consultations characterised as meetings between experts’. The underlying non-expert clinician’s theoretical underpinnings of SFBT (the antithesis of paternalism, whose limitations have been well documented\(^10\)) are in contrast to CBT models, which arguably could be construed as *applying* theories of pain management to people, with less of a focus on maximally exploring and utilising patients’ own views, hopes and expertise.

SFBT is a ‘younger’ therapy than CBT (it was formally coined around the late 1980s) and thus does not have as extensive an evidence base; nevertheless, a recent systematic qualitative review of outcome studies concluded that ‘SFBT is an effective treatment for a wide variety of behavioural and psychological outcomes’.\(^11\) There is limited specific evidence, however, for the effectiveness of SFBT in a chronic pain population, but related studies report positive outcomes. For example, one study\(^12\) reported that SF therapy, in conjunction with work hardening protocols, was effective for patients when developing effective coping responses to the stressors associated with orthopaedic rehabilitation (as compared to control groups). Thorslund\(^13\) found that SF group therapy increased the number of people who returned to work following a period of long-term sick leave as compared to a waiting-list control group (60% of people in the SF group compared to 13% of the control group). In addition, it was found that those in the experimental group worked more days and reported an increase in psychological health at a 3-month follow-up. There is evidence from the field of positive psychology that suggests psychological approaches that build self-efficacy and locate control within the person are likely to be useful for patients.
with chronic pain. For example, perceived control over pain has been shown to be associated with decreases in self-reported patient disability, pain intensity and depression.\textsuperscript{14} Self-efficacy in patients who had either low back pain\textsuperscript{15,16} or chronic temporomandibular pain\textsuperscript{17} has been shown to be inversely correlated with pain intensity and pain interference in daily life. Furthermore, evidence suggests that the perceived facilitating effect of pursuing other personal goals predicts the performance of a health-related behaviour over and above single behaviour-focused social cognitions.\textsuperscript{18}

**PMP: a community-based SF approach**

This section aims to describe a SF approach to PMP in a community setting, from assessment to evaluation.

**PMP assessment**

Patients are identified by community pain service clinicians as potentially able to benefit from the PMP when their goals involve wanting to maximise ‘living well’ despite chronic pain. They are seen initially in the service by a specialist physiotherapist and/or medical doctor to rule out any treatable disease and introduce the concept of pain management. As with all PMPs, the main aim is not necessarily to reduce pain (although this can happen for some people) but rather to build mobility, coping, self-management techniques, enjoyment of life, self-efficacy and hope. Patients are then sent a detailed letter inviting them to a group information morning, where they are able to meet other people who are considering attending the programme. Patients are given more information about what they might expect from the programme, and also have a one-to-one consultation with one clinician (clinical psychologist/occupational therapist/physiotherapist), and complete the pre-PMP questionnaires. The main SF aim and ethos of this ‘assessment’ or ‘information’ process is to explore whether the person’s best hopes for the group are roughly in line with the aims of the group.\textsuperscript{19} It is an inclusive approach. Other questions might also be asked, as the therapist (as the resource gatekeeper) has to feel confident that the person would be able to engage with a group process and also be prepared to commit to an 8-week course in principle. The therapist’s aim is to learn from the patient when judging this. Patient best hopes might include a wish to improve their sense of feeling able to cope, confidence, assertiveness, build more social contacts, mobility or ‘get out more’ to name a few examples. Also, patient strengths are noticed and amplified during assessment conversations — when has the person already managed pain well? The idea is to notice pre-PMP change. Importantly, patients can be offered a place if they are still hoping for a fix or a cure, provided they also wish to explore living the best life they can in the meantime, with the professional inviting the patient to explore this with them. This ‘meantime’ position or ‘twin track’ approach (used by Bold\textsuperscript{20}) helps acknowledge and respect the person’s ultimate hope of a ‘fix’ (be it attainable or not – and respecting the patient’s good reasons for holding onto a fix) and opens up possibilities for change. British Pain Society PMP proposed guidelines\textsuperscript{21} advise that ‘sometimes, medical treatment and pain management treatment are difficult for the patient to reconcile’ and ‘pain management components may be offered alongside treatments intended to eliminate or reduce pain’. A ‘twin track’ approach can help with this issue.

**The programme**

The 8-week programme is facilitated by the aforementioned multidisciplinary team, all of whom have received training in SF approaches and receive regular supervision in this approach from the clinical psychologist. The psychologist also delivers some sessions on the programme, often jointly with other members of the team, which allows for skill sharing and some opportunity to monitor the fidelity of the SF model of facilitation. The programme involves three sessions per week (two exercise sessions lasting 1 hour each, plus a 3-hour discussion/education session) with groups of up to 10 patients. There are additionally two hydrotherapy sessions in the last half of the programme (with opportunity for maintenance at public sessions), and links to an ongoing ‘drop in’ relaxation skills class. The exercise sessions are held in a community gym, exercises are replicable at home and there are links to exercise-on-prescription schemes post-PMP. The programme is delivered in the community with a local population with the aim of facilitating sustainable behaviour change and long-term well-being and to allow for the maintenance of social networks. During week 1, best hopes are further explored in depth, together with an icebreaker which draws on the SF principle of ‘problem-free talk’ (often helping patients recognise information about themselves, which is not pain dependent). Throughout the course, patients are frequently asked what they have been ‘pleased to notice’; again, the focus is on amplification of strengths.

The discussion/education sessions are held in a community health centre and are based on recognised biopsychosocial topics of pain management, such as energy management, mood and stress, acceptance and pain mechanisms, but the difference is the stance
– the topics are facilitated using a SF approach. For example, patients are asked to consider times they manage energy wisely, and, if it is on their agenda, how they would know if they were doing this better – they might even be invited to keep a diary of what works rather than a diary of what is difficult. The aim is to gain a ‘rich’ description from the patient. Clinicians are trained to explore and amplify what patients already know about living well, with the clinician positioned as an ‘expert by invitation’, offering advice when it fits with the patient’s established agenda. Group sessions are discursive rather than didactic. Each topic is followed by a relaxation or mindfulness ‘taster’ session delivered by a trained occupational therapist, with the aim of introducing patients to a range of techniques – discussion around what works for them as an individual is encouraged. Acceptance is explored with the SF facilitator again, being curious about whether this is something important to group members, and if so, what ‘good’ acceptance might look like for them … what would they be doing differently? Thinking? Feeling? What do they know about this already? This is a different stance from ACT which aims to teach techniques to help the patient achieve a position of acceptance. SF facilitation of this topic is more tentative and the facilitator waits to be invited by the patient. This often leads onto rich conversations around what is important to people in their lives and what things they would wish to see themselves focusing on (similar to the ACT process of identifying meaningful values).

Although the ethos of the PMP is solution focussed, patients naturally share experiences of their pain and the impact this has on their lives. Facilitators allow space and time for listening and acknowledgment. Their curiosity and questions, however, continue to lie not in investigating the problem but rather in continuing to notice strengths and possibilities. In this sense, the group is solution focused but not problem phobic.22

An interactive, evidence-based workbook compiled by clinicians and expert patients supports the topics facilitated during the course of the PMP. It forms a memory aid and is a source of information for friends and family members. SF questions and comment boxes in relation to specific topics encourage and prompt patients to self-reflect on their personal hopes and successes. A relaxation CD is also provided to further support patients to practise the techniques at home and build upon skills developed during the sessions. In line with the service ethos of utilising patients’ resources and expertise, the CD features a selection of techniques voiced and recorded by local expert patient volunteers with long-term health conditions, including members of our patient support group, Pain Clinic Plus.

**Sustained, resource-minimal care**

Patients frequently report the support of members of the group as highly important to them, and evidence suggests that social support helps to maintain behaviour change.23 The pain service has, therefore, sought to utilise this strength. The community setting of the service allows the development of structures to support continued group connections post-PMP (as advocated by the Chief Medical Officer’s Report4). For example, our occupational therapist runs a monthly drop in ‘booster’ session for any PMP patient, which explores ongoing best hopes and successes (and can also review PMP topics of the patients’ choosing if useful) as well as an ongoing drop in relaxation class – for PMP and non-PMP pain patients. There is also a support group (Pain Clinic Plus) which meets twice weekly, led by expert patients (one session incorporates chair-based exercise), and a well-being choir run by a pain patient for pain patients (her expertise as a singing teacher has been noticed and utilised!). These are two clear examples of how a SF approach is put into practice in the service, through noticing and believing in patient resources and utilising them meaningfully. Furthermore, links have been developed with a wide range of third-sector organisations, including the exercise links as described above. Due to the local setting, patients also develop their own networks and friendship groups and continue to meet informally. From the start of the PMP and throughout, patients are invited to consider what ‘living well’ after the course might look like for them. A group follow-up session occurs 10 weeks after the final week of PMP, which aims to explore through group discussion what is working and what ‘even better’ might look like.

**Service evaluation**

**Method**

**Design.** A pretest–posttest design was used to examine the effects of the 8-week multidisciplinary PMP (Service Evaluation registered with Southport and Ormskirk Hospital NHS Trust Audit and Effectiveness Department (Ref 12-314)). Baseline and post-PMP outcome measures included self-report pain self-efficacy, mental well-being, function and pain intensity and interference. Questionnaires were completed at the information morning, week 8 of the PMP and at the follow-up sessions, 10 weeks post final PMP session. Mailshots containing the questionnaires and prepaid return envelopes took place 6 and 12 months after completion of the PMP to evaluate long-term maintenance of effects.
Sample. Data gathered from 63 females and 22 males who had attended at least 75% of the 3 × 8 PMP sessions (i.e. the 3-hour discussion/education session plus two exercise sessions lasting 1 hour each) were included in the analysis. These components are considered as core aspects of the PMP, with additional hydrotherapy, drop-in relaxation classes and peer support meetings being optional ‘add-ons’ as part of the community pain service (CPS) patient-centred approach to pain management. Patients were diagnosed with a variety of chronic pain conditions and ages ranged from 28 to 83 years (mean = 54 years).

Outcome measures. In line with national PMP guidelines, improvements in emotional, social and physical factors were evaluated. A qualitative research study exploring patient experiences of this programme has also been conducted and is reported in a separate article.

Outcome measures were carefully selected for validity, reliability, sensitivity to change and user-friendliness (feedback was sought from Pain Clinic Plus). It was also important that they ‘fit’ (as far as possible) with the SF approach of growing well-being rather than measuring negative symptom reduction. (The service has also developed a patient-defined well-being measure, to be described in a future article.) Patients completed the following questionnaires:

- The Brief Pain Inventory–Short Form (BPI-SF) is a 11-item tool comprising a series of 0–10 numeric rating scales to assess the sensory intensity of pain and functional interference caused by pain. Four questions relate to pain severity with numeric rating scale (NRS) scores ranging from ‘0 = no pain’ and ‘10 = pain as bad as you can imagine’. Existing published clinical trials have assessed and reported pain intensity based upon the ‘worst’ and ‘average’ pain items singly. The use of single items is supported by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMPACT) recommendations for assessing pain. Pain interference is typically scored as the mean of the seven items relating to general activity, mood, walking, work, relationships with others, sleep and enjoyment of life. These items are presented as NRS ranging from ‘0 = does not interfere’ to ‘10 = completely interferes’. The British Pain Society recommends the use of the BPI to evaluate outcomes in clinical practice.

The 1-minute sit-to-stand test (STST) is a measure of physical functionality where participants complete as many sitting to standing positions as possible within a 1-minute period at a comfortable self-selected speed. The test was carried out by the physiotherapist during the first gym-based exercise session and repeated during the final exercise session and again during the 10-week follow-up group. The total number of complete repetitions was recorded. (It was not possible to gather 6- or 12-month data for function as per the other outcome measures as it is not possible to administer this test by mail!)

The Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) measures subjective well-being and psychological functioning through 14 positively worded statements addressing hedonic and eudaimonic perspectives of positive mental health. Higher scores (as indicated on 1–5 Likert scales) represent greater mental well-being. The WEMWBS has been validated for use in the United Kingdom using data from general population samples and focus groups. Mental health service users have been shown to prefer this measurement scale to other commonly used approaches.

The Pain Self-Efficacy Questionnaire (PSEQ) is a 10-item tool comprising a series of 0–6 Likert scales to measure patients’ confidence and beliefs in their ability to perform specific tasks and generalised pain-related constructs, such as coping despite the pain. Published evidence accumulated through a large cohort of chronic pain patients attending a PMP provides normative data and support for the tool’s psychometric properties.

Table 1 displays the means and p-values for data from each outcome measure at the different time points. Statistically significant differences were found for self-efficacy immediately post-PMP and at 10-week follow-up, for mental well-being at all time points.
post-PMP and for function at post and 10 weeks (later time points not measured).

Clinical significance. Previous research has reported an improvement of 9 points of the PSEQ as a minimal important clinical difference (MCID). The results, therefore, show clinically significant meaningful change following immediate completion of the PMP. The MCID of the WEMWBS varies considerably in the literature and a clinically significant result has been estimated at between 3 and 8 points difference. The mean improvements for scores on this measure in this evaluation are 7.9 and 10.6 at the post-PMP and 12-month follow-up data collection points, respectively, and there is sustained clinical improvement in well-being at all data points. On the BPI Pain Intensity scales measuring ‘worst’, ‘least’ and ‘average’ self-reported pain scores, clinically significant improvement has been considered to be any change of 2 points or more, and in line with the statistically significant findings, clinically significant change was not found for the BPI in this evaluation. An increase of 4 or more sit-to-stand repetitions for the within a 1-minute period for the STST has been described in the literature as a minimal detectable change score, and our results show sustained minimal detectable change at 10 weeks.

Missing data. Data collected during recent PMPs were included in the pre–post PMP comparison, and thus long-term follow-up data are yet to be accumulated for these cohorts. Taking into account only those patients who have been included in the 12-month questionnaire mailshots (as it has been more than 1 year since they completed the PMP), attrition rates for the PSEQ and WEMWBS were 48% and 39%, respectively, comparable to those reported in the literature. Of the studies included in the Cochrane review, the highest attrition rate for the 12-month data collected was 35%. It must be noted however that the present article describes an NHS service evaluation, as opposed to a formally conducted prospective research study. Reminder letters, telephone or data collection at a long-term follow-up group by a clinician would likely improve attrition rates; however, in this evaluation, it was only possible to send out the 6- and 12-month questionnaires once by post due to financial constraints and limited clinician time. Furthermore, of the outcome measures selected for evaluation, only the BPI has been validated for use in an interview format over telephone. 43

Table 1 shows that patients who completed the long-term follow-up questionnaires had slightly superior mean scores prior to commencing the PMP than the total sample mean at baseline. However, post hoc analyses of the WEMWBS pre-PMP data revealed no significant differences in baseline well-being scores between patients who returned the 12-month questionnaires and those who did not (t(62) = 1.97, p = .053). Conversely, for the PSEQ scores, a significant baseline difference was found (t(83) = 2.00, p = .049), suggesting that patients who provided the long-term data had significantly higher levels of pain-related self-efficacy prior to commencing the PMP than those who did not return the 12-month measures. It is possible that those patients who returned the long-term outcome data were more likely to improve upon their existing self-efficacy and/or maintain progress than those who did not respond to the 12-month mailshot. This could be considered a weakness of the evaluation’s overall findings. However, in view of the mixed findings of the post hoc tests, it is difficult to establish whether pre-existing group differences may have influenced long-term follow-up response rates. Similarly, the Cochrane review identified an array of published

| Table 1. Mean changes in self-efficacy, mental well-being, function and worst and average pain and pain interference from baseline (pre-PMP) to consecutive follow-ups. |
|---|---|---|---|---|---|---|---|
| | PSEQ (0–60) | Pre-PMP | Post-PMP | p-value |
| Post | 85 | 21.0 | 30.8*** | .001** |
| 10-week | 50 | 21.4 | 28.3 | .001** |
| 6-month | 38 | 22.7 | 26.0 | .064 |
| 12-month | 23 | 24.4 | 28.8 | .111 |
| WEMWBS (14–70) | | | | |
| Post | 64 | 35.8 | 43.7*** | .001** |
| 10-week | 35 | 37.0 | 42.8*** | .008* |
| 6-month | 28 | 39.1 | 42.4*** | .031* |
| 12-month | 14 | 40.6 | 46.4*** | .038* |
| BPI worst pain (0–10) | | | | |
| Post | 33 | 7.6 | 7.5 | .714 |
| 10-week | 15 | 7.3 | 7.7 | .324 |
| 6-month | 9 | 7.0 | 7.6 | .444 |
| BPI average pain (0–10) | | | | |
| Post | 33 | 6.3 | 6.2 | .635 |
| 10-week | 15 | 5.7 | 6.5 | .145 |
| 6-month | 9 | 5.4 | 5.7 | .708 |
| BPI interference (0–10) | | | | |
| Post | 33 | 6.9 | 6.7 | .434 |
| 10-week | 15 | 6.8 | 6.7 | .773 |
| 6-month | 9 | 6.2 | 5.5 | .081 |
| STST | | | | |
| Post | 70 | 9.0 | 12.6 | .001** |
| 10-week | 25 | 9.8 | 25.8*** | .001** |

PMP: pain management programme; PSEQ: Pain Self-Efficacy Questionnaire; WEMWBS: Warwick-Edinburgh Mental Well-being Scale; BPI: Brief Pain Inventory; STST: sit-to-stand test; MCID: minimal important clinical difference.

*Significant at .05; **significant at .001; ***MCID met.
studies which also reported baseline differences in outcomes (though these were excluded from the final review due to their elevated risk of bias, as were studies which did not investigate pre-existing differences as part of the data analyses). Should the service evaluation reported here lead to future formal research, differences in baseline outcomes should be examined and reported to acknowledge the potential risk of attrition bias and resources allocated to pursue collection of long-term data.

Discussion

This project aimed to evaluate outcomes of a community-based PMP delivered using a SF approach. It is an example of how biopsychosocial topics can be approached in a SF way, in a community setting, costing less than tertiary services.

An examination of baseline and subsequent follow-up data suggests that the PMP improved function, pain self-efficacy and mental well-being. Increasing patient self-efficacy through education programmes has been associated with better health status, lower costs to health-care systems and maintenance of long-term effects of rehabilitation. Improvements in mental well-being in this evaluation have been found to be maintained on a long-term basis, and statistically significant findings are supplemented by clinical significance. The findings are in line with the primary aims of the PMP.

Although improvements in mental well-being, self-efficacy and function were observed, no statistically significant improvements in self-report pain levels as measured by the BPI were found. It is not possible to directly compare these outcomes to those of the Cochrane review, due to the small scale nature of this evaluation, lack of comparison group and some different domains that were measured. However, the Cochrane review also found no effect on pain (as compared to active control) and found no or minimal lasting effects for catastrophising, pain, disability and mood (as compared to treatment as usual).

In this evaluation, the practice-based data give rise to high ecological validity, and the collection of long-term follow-up data is a particular strength. However, there was no waiting-list control group to control for extraneous and confounding variables. Intent-to-treat analyses of missing data were not conducted and only patients who provided complete pre- and post-PMP datasets (and subsequent 10-week, 6- and 12-month follow-up data, where available) were included in this analysis. The evaluation also did not control for social desirability bias, as the clinicians who delivered the programme also collected and analysed the data. These factors may reduce internal and external validity.

Conclusion

This service evaluation suggests that locally, a SF, community approach to PMP has had a positive impact for pain patients. The results suggest that a SF approach is potentially as effective as other methods, possibly more, and there also appear to be advantages to a community setting, with the concurrent opportunities for long-term support and social networking. Future evaluation/research should build upon the existing findings to encompass a larger sample and continued collection of long-term data.

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Conflict of interest

The authors declare that there is no conflict of interest.

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