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Soles of the Feet Meditation Intervention for People with Intellectual Disability and Problems with Anger and Aggression—a Feasibility Study

Judith L. Roberts¹ · Jonathan Williams² · Gemma Maria Griffith³ · Robert S. P. Jones¹ · Richard P. Hastings⁴ · Rebecca Crane¹ · Lucy Bryning⁵ · Zoe Hoare⁶ · Rhiannon Tudor Edwards⁵

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Abstract

Objectives Mindfulness-based programs (MBPs) such as the ‘Soles of the Feet’ (SoF) meditation have been shown to be effective for reducing aggressive behavior in people with intellectual disabilities (ID). Research on SoF has shown promising results in the USA but there is an absence of evidence for the approach in the United Kingdom (UK). The aim of this research was to adapt SoF for the UK and to assess the feasibility and cost of implementing the SoF intervention in a UK healthcare setting (UK SoF).

Methods The UK SoF intervention consisted of a manualized protocol delivered over a six-week period by National Health Service staff to people with ID and their carers. This was a single-arm study with three measurement time points (baseline and 2- and 6-month follow-ups).

Results The UK SoF intervention was shown to be feasible, with recruitment, retention, and adherence figures exceeding the minimum cut-off of 50%. Costs were £2426 per participant, or £2766 when including set-up costs such as therapist training. Although not a primary aim, data suggest that at 6-month follow-up, there was a reduction in scores for anger and aggressive behavior, and depression and anxiety showed improvement. In addition, people with ID were able to self-report on their health-related quality of life.

Conclusions This study has indicated areas where the protocol could be further improved, and it is recommended that the research should move to a pilot trial before the development of a full randomized control trial.

Keywords Intellectual disability · Mindfulness · Aggressive behavior · Feasibility study · Costs

Approximately 20% of adults with an intellectual disability (ID) engage in some form of challenging behavior (Bowring et al. 2017; Jones et al. 2008) which commonly includes aggressive behavior towards other people or property/objects.

Aggressive behavior occurs for 8.3% of adults with ID known to services (Bowring et al. 2017) and is persistent over time (Totsika et al. 2008). For example, Totsika et al. found that 70% of adults with ID engaging in significant aggressive

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✉ Judith L. Roberts
Judith.roberts@bangor.ac.uk

¹ School of Psychology, Bangor University, Brigantia Building, Penrhallt Road, Bangor LL57 2AS, UK

² Child and Adolescent Mental Health Service, Rhyl, Denbighshire, UK

³ Centre for Mindfulness Research and Practice, School of Psychology, Bangor University, Brigantia Building, Penrhallt Road, Bangor LL57 2AS, UK

⁴ Centre for Educational Development Appraisal and Research: (CEDAR), Warwick University, Coventry, England CV4 7AL, UK

⁵ Centre for Health Economics and Medicines Evaluation (CHEME), Bangor University, Bangor, UK

⁶ North Wales Organisation for Randomised Trials in Health (NWORTH), Bangor University, Bangor, UK

behavior towards others were still engaging in aggressive behaviors 11 years later.

Aggressive behaviors are harmful to the individual engaging in the behavior, other people, and/or the environment. In addition, these behaviors may negatively affect carer well-being (Hastings 2002) which can impact on home and work placements. The impact of aggressive behavior may lead to limited access to health and social services and reduce opportunities to engage in community services (Emerson 2001). Admission to intensive and specialist residential services is costly, and aggressive behavior may negatively impact on required staffing levels to manage incidents, placing further strain on already under-resourced services (Singh et al. 2008a). With limited health and social care budgets, there is a strong economic case for investing in public health initiatives including those for preventing violence (Nurse et al. 2014).

Whilst aggressive behavior may be maintained by environmental contingencies, Tenneij and Koot (2008) found evidence to suggest that anger is implicated in some forms of aggressive behavior. Similarly, Taylor et al. (2005) found that self-reported anger was positively associated with levels of aggression in an inpatient setting. Engaging in verbally or physically aggressive behaviors can lead to unwanted outcomes; some people with ID report that they feel regretful and that they find their anger and challenging behavior aversive (Griffith et al. 2013). Thus, methods to intervene to reduce aggression and anger are an important focus for both research and practice.

A range of psychological therapies have shown promising results for people with mild-to-moderate ID (Beail 2017). A meta-analysis of eight anger management intervention studies for people with ID by Hamelin et al. (2013) showed that the psychological therapies used primarily involved cognitive restructuring, problem-solving exercises, and relaxation techniques. The study authors found medium-to-large effect sizes suggesting the effectiveness of such interventions, although the authors concluded that the lack of controlled research in this area challenges the strength of these findings. Such criticism has been somewhat addressed by subsequent randomized controlled trials (RCTs) which have demonstrated the effectiveness of a group-based cognitive-behavioral intervention for anger control for people with ID (Willner et al. 2013) and a Mindfulness-Based Program (MBP), called Soles of the Feet (SoF), which demonstrated a significant reduction in physical and verbal aggression in people with ID (Singh et al. 2013). Given the paucity of RCTs in this field, it is clear that further work needs to be done in this area.

Increasingly, MBPs are being developed for people with ID, with promising indicators of their effectiveness and their acceptability for this population (Chapman et al. 2013; Robertson 2011). Gore and Hastings (2016) suggested that MBPs can be adapted for adults with ID and that such approaches may remove some of the cognitive load of more

traditional cognitive behavioral methods. As already noted, people with ID find their anger aversive (Griffith et al. 2013), and in an earlier study, Ruef and Turnbull (2002) found that adults with ID are keen to learn how to self-manage anger; mindfulness practice could provide this level of autonomy. MBPs such as SoF for people with ID are, therefore, of particular interest.

Much of the research exploring the outcomes of MBPs for people with ID focus on the behavior that the intervention aims to change (e.g. Chapman et al. 2013). According to Kiken et al. (2015), trait mindfulness is the “predisposition to be mindful in daily life” (pg.41). Kiken et al. state that heightening state mindfulness with regular mindfulness practice over time can increase trait mindfulness. If the aim of an intervention is to develop a regular mindfulness practice, therefore increasing trait mindfulness, there needs to be an appropriate measure to quantify these changes. There are several questionnaires that are used to measure trait mindfulness (Baer et al. 2006; Bergomi et al. 2013; Chadwick et al. 2008;), yet these are cognitively demanding and would prove challenging for people with ID. A database search in February 2020 for a validated measure via Web of Science, Psychinfo, and ScienceDirect using the following terms ‘questionnaire’, ‘scale’, ‘mindfulness’, ‘intellectual disability’, and ‘learning disability’ did not produce a suitable questionnaire.

A number of small-scale studies have demonstrated the success of SoF with people with ID who have aggressive behavior with reductions or elimination of aggressive behaviors at long-term follow-up (Adkins et al. 2010; Singh et al. 2007; Singh et al. 2008a; Singh et al. 2011b). Singh’s SoF intervention (Singh et al. 2003) has primarily been researched in the USA, involves extensive training, and includes little in terms of a taught psychoeducational component regarding emotional problems or about mindfulness (Griffith et al. 2016). Additionally, SoF delivery in the USA demonstrated significant cost savings as a result of a reduction in staff absenteeism (Singh et al. 2008a). As this may not be representative of costs in a United Kingdom (UK) healthcare setting, a health economic evaluation is necessary.

In many healthcare settings, including the UK National Health Service (NHS), psychological interventions are typically delivered by a therapist on a one-to-one basis and over a time-limited number of weekly/regular sessions. In the present study, Singh’s SoF manual was adapted for UK NHS settings to include a full description of session-by-session content, with an educational component about anger, aggression, and mindfulness. As noted by Bowen et al. (2009) where there is a lack of, or limited evidence base of an intervention, the feasibility of adapting and delivering such an approach, including a health economic evaluation, should precede any study of effectiveness.

The current study aimed to test the feasibility of the UK SoF mindfulness-informed intervention and research process

and focused on testing the fit of this approach in a real-world setting (Bowen et al. 2009). This included referral pathways—i.e., numbers of participants and carers recruited and the willingness of clinicians to refer potential participants and the process of delivery across NHS sites; the *acceptability* of the intervention evidenced by willingness of clinicians to be trained in the approach; the *accessibility* evidenced by outcome and process measure completion rates; and intervention *adherence* by tracking the number of participants who completed the intervention. Having developed a new protocol, it was necessary to check the feasibility of implementation through monitoring and assessing intervention fidelity. The study also aimed to develop and carry out a preliminary test of the acceptability and accessibility of the Mindful Awareness for Adults with an Intellectual Disability Scale (MAIDS) with further analysis of reliability and validity if positively indicated. We also calculated the costs of the UK SoF intervention and evaluated the acceptability and validity of the health economic outcomes (Griffith et al. 2016).

Method

Participants

The mean age of the 19 participants was 34.8 years (SD 8.93), consisting of 12 males (63.2%). The presence of an ID was assessed through administration of the Wechsler Abbreviated Scale of Intelligence–2nd Edition (WASI-II; Wechsler, 2011: $M = 57.15$, $SD = 7.39$) and the Adaptive Behavior Assessment System®–2nd Edition (ABAS; Harrison and Oakland 2003: $M = 63.24$, $SD = 7.10$). Carers who supported participants were either family members ($N = 9$), or paid support staff ($N = 10$). Participants were identified by NHS clinicians employed by a single UK health organization. Inclusion criteria were that participants were 18 years old or over, that the presence of an ID was confirmed, that there were clinically significant difficulties with anger control as assessed by their clinician, that the participant was able to give informed consent, and that a family member or paid carer could be available to be with the participant during intervention sessions, who had supported them for a minimum of 6 months, and who provided a minimum of 2-h support per week. Although language ability was not an inclusion criterion, the ability to give informed consent indicated that the participant would also have the language level needed to participate in the UK SoF intervention. Exclusion criteria were an existing diagnosis of Autism Spectrum Disorder (ASD) due to potential difficulties the participant with ID and the addition of an ASD diagnosis might have with more abstract concepts, that there was the presence of mental health problems or behavior that would prevent the participant from interacting with the therapist or carer or retaining information (e.g., dementia, active

psychosis), and individuals who were in receipt of another direct psychological intervention at the time of the study (e.g., relaxation training, dialectical behavior therapy, cognitive behavior therapy).

Procedure

An initial screening visit (by a trained researcher) sought informed consent. Data were collected during face-to-face sessions with the researcher at the participant's home or a place of their choice (e.g., their local clinic). Following the initial screening visit, a baseline visit occurred prior to the commencement of the intervention. Within 2 weeks of baseline measure completion, the intervention began and was delivered to the participant by a trained therapist employed by the NHS. Follow-up visits took place at 2 and 6 months post-baseline.

Soles of the Feet Intervention

Development of the UK SoF intervention manual, therapist training, and supervision is described in Griffith et al. (2016). It is important to note that this UK SoF is a mindfulness-informed program which shares theoretical underpinnings with MBPs, but places less emphasis on “systematic and sustained training in ... mindfulness meditation practices (for both teacher and participants)” (Crane et al. 2017, p.991). The UK SoF manual was specifically designed for use by clinical staff working with people with ID in NHS settings in the UK and was based on the work of Singh et al. (2008b). The manualized intervention was delivered once a week over a 6-week period. Each session took around 90 min, with comfort breaks relevant to participants' needs. Participants were given a workbook that was theirs to keep. Psychoeducational material from each session could be kept in the workbook. An audio recording of the SoF meditation was provided in a format best suited to the participant. Participants were asked to listen to the recording on a daily basis and to practice the meditation that had been discussed in the session that week. The weekly session outline is shown in Table 1.

Measures

Initial Screening Visit

Following the consent process which included a capacity to consent assessment (Arscott et al. 1998), information on age, gender, and current residential status was gathered during the baseline visit. The presence of an ID was confirmed by using the WASI-II which is a measure of IQ in adults and the ABAS which is a measure of abilities, skills, and physical and sensory impairments which was completed by the carer.

Table 1 Overview of sessions

Sessions	Main aims	Brief outline
1	Introduction to the intervention—getting to know the client/therapist/carer	Introduction to mindfulness; posture/breathing practices; introduce anger as the focus of the intervention; psycho-education around what anger is, why we get angry, and when it happens; clarify hopes
2	Getting to know the soles of your feet!	How does mindfulness help us when we are feeling angry? Practicing the Soles of the Feet meditation during a neutral or happy situation
3	Using the Soles of the Feet meditation in angry situations	Focus on what makes us angry: what, where and when; practicing the Soles of the Feet in a situation that causes anger
4	Using the Soles of the Feet meditation for triggers to anger	Focus on using Soles of the Feet mediation just before getting angry. What are the triggers?
5	Review and problem solve	Problems with regular practice? Exploring barriers and challenges, revisit hopes from session 1, normalize difficulties in practicing regularly/no changes yet, revisit how being mindful helps
6	Progress so far and the way ahead	Focus on practice, the final session is about reaffirming why it is important to practice, final problem-solving session, recognizing successes, how to continue alone

Participant Measures (Administered at Baseline and Follow-Ups)

All self-report measures used had been adapted for use with an ID population, or had been evaluated by the research team and were deemed appropriate measures for people with ID. Due to the complexity and length of some measures, e.g., Novaco Anger Scale (60 items), participants were told that they could stop or take a break at any time. Due to the likelihood of literacy problems, the questions were read to everyone, and participants were told that there were no right or wrong answers and that they could ask questions at any time. This is consistent with the process followed by Novaco and Taylor (2004).

Novaco Anger Scale (NAS; Novaco and Taylor 2004)

This is a 60-item scale exploring the experience of anger, with three subscales—Cognitive, Arousal, and Behavioral—that constitute a total score for anger disposition. Items are rated on a 3-point scale ‘1—never true’, ‘2—sometimes true’, and ‘3—always true’. Novaco and Taylor report the NAS as having good internal consistency (.92) although test–retest reliability is low (.52). Novaco and Taylor acknowledge that test–retest reliability is low, but due to ongoing participant treatment in their validation study, consistency in anger rating would fluctuate, leading to a lower correlation between repeated administrations across the study time period and therefore low test–retest reliability.

Provocation Inventory (PI)

This is a 25-item scale that lists a range of situations that induce anger. Participants rate various situations from ‘1’ (not at all angry) to ‘4’- (very angry). The PI was developed

to accompany the NAS and is suitable for use with people with ID. Novaco and Taylor (2004) again modified the items to improve clarity or simplify meaning and report the PI as having good internal consistency (.92) although test–retest reliability is low (.57). The NAS description gives a rationale for this.

The Glasgow Depression Scale for Adults with Learning Disabilities (GDS-LD)

This is a 20-item scale which asks how often a symptom has occurred over the past week. Respondents can answer ‘Never’, ‘Sometimes’, or ‘Always’ to each item. According to Cuthill et al. (2003), the GDS-LD has high internal consistency ($\alpha = 0.90$) and good test–retest reliability ($r = 0.97$).

The Glasgow Anxiety Scale for Adults with Intellectual Disabilities (GAS-ID)

This is a 27-item self-rating scale that assesses how often a symptom has occurred over the past week. Respondents can answer ‘Never’, ‘Sometimes’, or ‘Always’ to each item. Mindham and Espie (2003) report good test–retest reliability ($r = 0.95$) and internal consistency ($\alpha = 0.96$).

EuroQol Five-Dimensional Questionnaire–Youth Version (EQ-5D-Y; EuroQol Group, 1990)

This is a standardized and validated instrument on health-related quality of life which is intended for use with children aged between 8 and 15 years old. This is a brief questionnaire that has five items related to mobility, self-care, usual activities, pain and discomfort, and anxiety and depression. Each item is rated as either ‘no problems’, ‘some problems’, and ‘a

lot of problems’. The EQ-5D-Y also includes a visual analogue scale where the participant rates their overall health on a scale of 0 to 100 where 100 represents the best health imagined. Test–retest reliability in children is between 69.8 and 99.7% with internal consistency as $\alpha = 0.67$. No psychometric data are available for people with ID. Due to the absence of a health-related quality of life questionnaire for people with ID, this measure was considered appropriate by the research team.

Child Health Utility 9D Index (CHU-9D; a Pediatric Generic Preference-Based Measure of Health-Related Quality of Life)

This is intended for use with children aged 7–17 years (Stevens and Ratcliffe 2012). This measure consists of 9 items, with 5 possible responses from 1 to 5 that assess that days functioning in domains of worry, sadness, pain, tiredness, annoyance, school (changed in this study to ‘work/college’), sleep, daily routine, and activities. There are no psychometric data on the use of this measure with people with ID.

Icepop Capability Measure for Adults (ICECAP-A)

This is a measure of capability for the general adult (18+) population for use in economic evaluation. Unlike most profile measures used in economic evaluations, the ICECAP-A focuses on well-being defined in a broader sense, rather than health (Al-Janabi et al. 2013). The measure consists of 5 areas of well-being related to feeling secure, relationships, independence, achievement, and pleasure. There are 4 possible responses to each area where 1 is the absence of quality of life and 4 indicates the best quality of life. There are no psychometric data on the use of this measure for people with ID.

Mindful Awareness for Adults with an Intellectual Disability Scale (MAIDS)

The MAIDS questionnaire consists of 10 items to assess trait mindfulness of individuals with ID. As this was the first measure of its kind, the MAIDS was developed by conducting a review of the literature and through discussion amongst the research team. This questionnaire was based on the five facets of mindfulness (Baer et al. 2008): (1) observation, (2) describing, (3) awareness, (4) non-judgment, and (5) non-reaction to inner experience. Each facet are related to two of the MAIDS items. An example item for ‘observation’ was “I notice when I feel sad”. To account for respondent biases, four of the questions were worded negatively. The questions were presented in simple sentences and the participants had three options to respond: (1) yes, (2) do not know, and (3) no. An example is item 10: “Feeling scared is bad”. This question relates to the facet ‘non-judgment’, and a ‘yes’ response would indicate judgement resulting in a score of zero (i.e., lower mindfulness). Scoring for the MAIDS ranged from a minimum

possible score of zero to a maximum possible score of 20 (high scores indicating better mindfulness). Items 3, 4, 6, 9, and 10 were reverse scored.

Proxy Report Measures (Administered at Baseline and Follow-Ups)

The Modified Overt Aggression Scale (MOAS: Oliver et al. 2007) measures four types of aggressive challenging behaviors over the previous week (verbal, against objects, against self, against others), and measures both severity and frequency. The MOAS has good internal consistency and test–retest reliability ($\alpha = 0.75$) for the rating of aggression. The MOAS was administered to the carer by the clinician delivering the intervention on a weekly basis. Carers also completed proxy versions of the EQ-5D-Y, CHU-9D, and ICECAP-A so that their perception of the quality of life of the participant was measured. In addition, the following measures were utilized:

The Glasgow Depression Scale–Carer Supplement (GDS-CS)

This is a 16-item scale that asks how often symptoms of depression have been present over the previous week. Respondents can answer ‘Never’, ‘Sometimes’, or ‘Always’ to each item. Cuthill et al. (2003) report high internal consistency ($\alpha = 0.93$).

Anxiety, Depression, and Mood Scale (ADAMS)

As there is no equivalent of the GDS-CS for anxiety, the ADAMS general anxiety scale was utilized as a proxy report measure (Esbensen et al. 2003). The 28-item scale is completed by a caregiver who knows the participant well. There are five subscales: Manic/Hyperactive Behavior, Depressed Mood, Social Avoidance, General Anxiety, and Compulsive Behavior. Ebensen et al. report good internal consistency ($\alpha = 0.83$).

Client Service Receipt Inventory–European Version (CSRI-EU)

This has previously been used in ID research, and is a measure of the participant’s use of medication and health care, social care, and day and community services (Chisholm et al. 2000).

Feasibility Process Measures

The primary measures of interest were recruitment, attrition, and response rate for questionnaires. Bowen et al. (2009) suggests that the primary aim of feasibility studies is to determine whether the intervention is acceptable, accessible, and whether participants adhere to the protocol. In line with the relevant areas of focus outlined by Bowen et al., i.e., acceptability, demand, implementation, adaptation, and integration, these

measures focused on screening and recruitment rates, drop-out rates, and questionnaire completion rates.

Intervention Fidelity

A fidelity checklist was designed specifically for use with the UK SoF intervention. For this study, two sessions were audio-recorded for each participant. These were randomly assigned at the beginning of the study, ensuring that each of the possible six sessions was recorded at least once. The fidelity checklist consisted of two parts and based on methods used in previous ID research (Jahoda et al. 2017). Part one was a checklist of 11 items that should have been covered in each session (adherence) (e.g., item 11—home practice set). Responses were either a Yes or No; therefore, a maximum total score for part one would be 11. Part two of the checklist referred to delivery of the key intervention components by the therapist (delivery) (e.g., session 1—“therapist introduces themselves and explains their role”). Part two of the checklist consisted of individual checklist items (yes/no response) for each session. The total possible maximum score for each session was as follows; session 1 = 27, session 2 = 18, session 3 = 15, session 4 = 15, session 5 = 14, and session 6 = 15. Each session consisted of a different number of key intervention components which resulted in a variation in individual checklist items. A percentage adherence score was therefore calculated for part two of the checklist (yes/no × 100). Two independent raters completed the fidelity checklist for a sample of session recordings to measure inter-rater reliability. The independent raters were research project support officers, both of whom had graduated at degree level and who had experience of mindfulness (rater 1) and of working with people with ID (rater 2). Both raters were involved in developing the fidelity measure and attended training for NHS clinicians delivering the intervention. Training in using the fidelity measure was provided by the research team.

Data Analyses

This feasibility study was a single-arm study with three measurement time points: (1) baseline, (2) immediately after the intervention (2 months post-baseline), and (3) follow-up (6 months post-baseline). Qualitative data was also taken at follow-up and is reported in Griffith et al. (2019). Feasibility metrics (e.g., recruitment and retention rates, clinical characteristics, duration of the intervention) were analyzed, together with adherence outcome, participant acceptance, and adherence to the intervention. No hypotheses were tested, and no formal analysis of outcome variables was made as the study was not powered for definitive analysis. However, the mean change from baseline together with associated variances was calculated for all measures and presented as point estimates together with 95% confidence intervals. An estimation of the

precision of the means and variances will inform the power calculation of any future RCT protocol. No imputation or pro-rating of missing data occurred over and above that stipulated by the scoring routines for the measures, due to the feasibility nature of the study.

Health Economic Evaluation

The health economics component of the study was conducted from a public sector multi-agency perspective (Drummond et al. 2015). As there is limited evidence of self-report health-related quality of life and service-use questionnaires being used in an ID population, the principle aims of the health economics component of this feasibility study involved piloting the key outcome measures, assessing completion rates and comparing self-report and proxy ratings.

Costing the Soles of the Feet Intervention

The intervention was costed using micro-costing techniques that have previously been successfully used in costing MBPs (Bryning et al. 2015; Edwards et al. 2015; Kuyken et al. 2015) and other complex psychosocial interventions (Charles et al. 2013). The mean unit delivery costs of running the intervention such as session delivery time, staff travel, and participant resources were extracted from cost diaries completed by one of the intervention therapists. In addition, it was necessary to gather cost data from additional sources to establish costs of the intervention development and setup costs such as staff training. National unit costs (2016/17) were applied where available (Curtis and Burns 2017; NHS Improvement 2018), and we referred to the study manager when these costs were unavailable (e.g., for core therapist resources including the production of the course manual).

Assessing Costs of Service Use

Patterns of health care, social care, and other service use over the preceding 4 months (at each study time point) were explored and costed using national unit costs (Curtis and Burns 2017; NHS Improvement 2018) (see Appendix D in [supplemental materials](#) for unit costs and sources). A period of 4 months was deemed sufficient for a representative picture of service use to be gauged, yet recent enough for the respondent to recall accurately the frequency and nature of contacts (Roberts et al. 1996; Ritter et al. 2001). As the intervention follow-up period is less than 1 year, it was not necessary to discount costs (Drummond et al. 2015).

Results

Figure 1 shows the flow of recruitment. Of the 26 eligible participants identified, three were not eligible for participation, and two could not be contacted. Following consent, one participant withdrew and one could not be contacted following the initial visit. Nineteen participants completed baseline measures and were allocated a therapist for the intervention phase.

Appendix A ([supplemental materials](#)) gives the demographics of the sample. The majority of participants were single, white, male, and did not identify as being Welsh speaking.

There was a fairly even split of paid carer versus family member (53% to 47%, respectively) supporting the participant.

Feasibility Outcomes

Table 2 indicates the primary outcomes of the study relating to recruitment, retention, and adherence. Recruitment of participants from those identified as eligible was 90.5%. Of those screened, 80% were recruited. This indicates identification of appropriate screening pathways and a high level of participant sign-up to the study. There were three participants who were ineligible. The first of these had an IQ over 75, and diagnoses

Fig. 1 Flowchart of recruitment

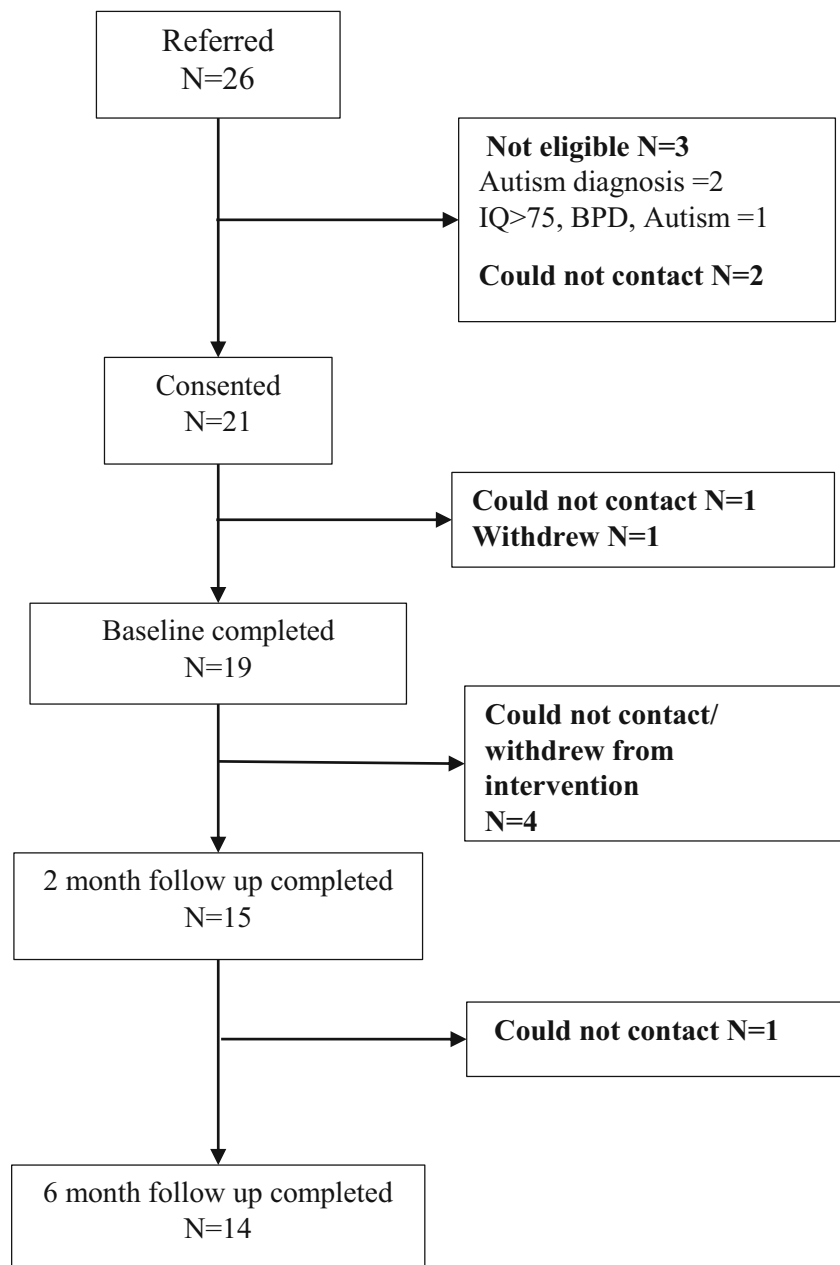


Table 2 Outcomes related to feasibility of the study

Primary outcomes relating to feasibility	Sum or %
The number of potential participants screened for eligibility	26
The number of ineligible participants	3
Number of potential participants who could not be contacted	2
The number of eligible participants	21
The number of eligible participants who did not take part	2
Number completed at baseline	19
<i>Recruitment rate</i>	<i>90.5%</i>
Number withdrawn during the intervention	5
Number completed (2-month follow-up)	15
Number completed (6-month follow-up)	14
Retention rate at 2 months	78.9%
<i>Retention rate at 6 months (from baseline)</i>	<i>73.7%</i>
<i>Adherence rate (those who completed the intervention)</i>	<i>73.7%</i>

of autism and borderline personality disorder. The remaining two both had diagnoses of autism. Two potential participants were deemed eligible but did not take part. Both were matched with therapists; one person proved difficult to contact while the other upon contact doubted they would have time to commit and had changed their mind about participating.

Missing Data and Inconsistency Measures

Appendix B (supplemental materials) depicts the numbers of completed measures recorded at each time point. None of the scoring routines for the measures stipulated rules for handling missing items; therefore, if one item was missing, the measure was considered incomplete, and a score was not calculated. The measures were tolerated well with evidence that if a participant started a measure, they would complete it. The CHU-9D appeared to have the lowest completion rate with the ‘Work/College’ item causing the most problems.

Outcome Results

Table 3 provides the raw score descriptive statistics for each of the outcome measures recorded at each of the time points. Paired samples *t* tests were completed for baseline to 2-month and 6-month follow-ups. Table 4 presents the mean differences achieved pre to post, associated 95% confidence interval, effect size, and an indication of the direction of the change. Mean changes were calculated as baseline score minus follow-up time point; therefore, an increase in the measure is denoted by a negative mean difference. For the majority of measures, a positive result would be to see a reduction in score (thus a positive mean difference in the table). For EQ-5D-Y, ICECAP-A, and CHU-9D an increase in the measure is

positive, and therefore, a negative mean difference value would be preferable.

In Table 4, the mean difference between the time points has been interpreted in terms of being in favor or not of SoF. For the initial post intervention comparison, it was evident that the change was positive for the specific measures and not for the more generic measures. The directional effect was less clear at the longer follow-up time point which would be looking at maintenance of effect beyond those being provided by the initial treatment period.

All results are based on small samples and care needs to be taken in drawing conclusions. For example, the GDS proxy in particular, was completed by very few carers (six completed cases for initial comparison and reducing to three for the longer term follow-up). Simple effect sizes are also given in Table 4. These have been calculated as Cohen’s *d* and represent the effect size seen in pre-to-post measurement. These effect sizes are indicative of a pre-to-post change rather than a between-group effect size that may be seen in an experimental design study.

Intervention Fidelity

Of the 14 participants who fully completed the 6-week intervention, a total of 24 sessions from a potential 28 were recorded. Of these, a total of 13 randomly selected recordings were rated by two independent, trained raters for reliability analysis. Average absolute agreement was established using a two-way, mixed model ICC on summary scores for part two (delivery) of the fidelity checklist which was 0.71. According to Koo and Li (2016), this indicates moderate reliability (range .5–.75). This suggests that single rater scores on this section of the fidelity checklist are a reliable measure. Intervention fidelity ratings on a sample of 13 recordings on part one of the fidelity checklist showed that on average, 84.64% of the 11 items stipulated for each session were covered. Across the same sample of recordings, on average, 80.15% of the key components for each session were delivered indicating a high level of fidelity for both adherence and delivery.

Mindful Awareness for Adults with an Intellectual Disability Scale (MAIDS)

As the primary aim of the current study focused on the feasibility of delivering the UK SoF intervention it was also prudent to explore the acceptability and accessibility of the MAIDS questionnaire prior to any further validation analysis. A number of problems arose, specifically with individual items. The majority of the sample answered ‘yes’ to question 1 “I am good at listening” across all three time points (16/19, 14/15, and 14/14, respectively) suggesting that this was a demand characteristic. Question 6 “I wish I could be happy all the time” prompted all but 2 respondents to respond ‘yes’ (1

Table 3 Descriptives for the outcomes at each time point (raw scores)

Outcome	Baseline				2-month follow-up				6-month follow-up			
	N	Mean	SD	Obs. range	N	Mean	SD	Obs. range	N	Mean	SD	Obs. range
MAIDS	19	9.58	2.95	1–14	15	10.87	2.39	7–14	14	11.86	2.48	8–17
Novaco anger raw-score	18	94.80	17.19	65–118	14	84.41	18.60	58–120	14	85.89	17.82	63–115
Novaco provocation raw score	13	68.54	19.08	35–91	12	59.83	13.33	40–83	14	64.29	14.49	42–90
Glasgow depression score	17	13.35	7.23	2–28	13	10.15	5.05	4–18	14	13.57	7.51	3–25
Glasgow anxiety score	18	23.00	7.66	11–42	12	18.92	8.59	8–34	14	21.29	9.45	7–36
EQ-5D index	19	0.82	0.21	0.41–1	15	0.82	0.29	0.09–1	14	0.75	0.34	–0.04–1
EQ-5D VAS	19	69.58	32.77	0–100	15	75.60	22.03	35–98	14	76.07	22.69	30–100
ICECAP-A	19	0.81	0.21	0.28–1	14	0.83	0.19	0.41–1	14	0.86	0.16	0.41–1
CHU-9D	11	0.91	0.05	0.83–1	6	0.89	0.05	0.83–0.96	10	0.90	0.10	0.70–1
MOAS	18	4.22	5.12	0–18	14	1.71	3.07	0–11	9	2.44	2.60	0–8
Weighted MOAS	18	9.06	12.89	0–42	14	3.07	6.04	0–22	9	4.78	6.16	0–18
Glasgow depression score proxy	11	8.45	5.09	1–18	11	10.09	6.17	2–22	5	9.20	5.59	4–17
ADAMS manic	17	5.41	2.27	2–11	14	5.07	2.92	2–11	7	4.71	2.98	1–10
ADAMS depressed	15	5.13	2.72	0–11	12	6.08	4.38	1–15	8	7.25	6.56	1–19
ADAMS avoidance	18	5.67	3.61	0–12	12	5.08	3.32	0–11	7	7.00	6.08	0–16
ADAMS anxiety	18	8.28	4.65	1–18	14	7.29	4.63	0–16	6	6.00	3.41	2–10
ADAMS obsessive	16	2.75	2.32	0–8	13	1.92	1.32	0–5	7	2.00	2.24	0–6
EQ-5D index	18	0.72	0.19	0.31–1	14	0.64	0.31	–0.03–1	7	0.63	0.28	0.18–1
EQ-5D VAS proxy	16	73.38	22.95	40–100	13	73.54	19.48	35–100	7	70.14	16.89	40–95
ICECAP-A proxy	17	0.76	0.14	0.53–0.92	14	0.72	0.16	0.53–1	9	0.72	0.11	0.53–0.88
CHU-9D proxy	11	0.86	0.11	0.69–1	8	0.87	0.11	0.65–1	6	0.80	0.08	0.68–0.88

responded ‘no’ and 1 responded ‘do not know’) at baseline, 14/15 (93%) at 2-month follow-up, and 12/14 (86%) at the 6-month follow-up. Possible confusion was indicated regarding the responses for Q7 “I can find the right words to say that I am angry” and Q9 “I cannot find the right words to say I am angry”. At baseline, 7/19 respondents (37%) gave the same answer ‘yes’ to both. At 2 months, 6/15 respondents (40%) gave the same answer (a mixture of ‘yes’ and ‘no’) to both. At 6 months, 4/14 respondents (29%) gave the same answer to both (a mixture of ‘yes’ and ‘no’). Direct observation of participants’ responses to the questionnaire also suggested that constructs (e.g., ‘hot’, ‘cold’, ‘angry’) rather than the concept of awareness may have driven replies. Due to these issues, further reliability and validity analyses were not considered useful. Mean scores are shown in Table 3, but these should be considered with caution.

Health-Related Quality of Life Measures

From a health economic evaluation perspective, it was of interest whether the included health-related quality of life outcome measures were appropriate for this study population. The individuals with ID were able to self-report on their health-related quality of life using the EQ-5D-Y and the ICECAP-A. However, the CHU-9D (a measure which is

designed for children over the age of 7) resulted in difficulties leading to more missing data. One interesting observation was that mean participants’ self-reported health-related quality of life was consistently higher than mean proxy ratings across all time points on all outcome measures. As this was a very small sample, no formal statistical analysis was conducted. However, further investigation is warranted to assess the construct validity of measures in this population and level of agreement between proxy and self-report utility measurement.

Intervention Costs

Following the development of the UK SoF manual, the total costs to set up and deliver the intervention within the feasibility study were £55,361 (total set up costs £9276 plus total delivery costs of £46,085—see Appendix C (supplemental materials) for base case costing). This excludes the cost to adapt and develop the manual for a UK setting (estimated to be approximately £21,008 in research and initial development costs). Intervention setup costs included the initial therapist training (plus any associated staff backfill) and the purchase of therapist course materials. The initial training cost was £565 per therapist with a total of 16 therapists completing their training as part of the feasibility study. Course materials were purchased for therapists to use during the delivery of the

Table 4 Estimated mean differences of paired sample *t* tests between baseline and post measurements

Outcome	Baseline to 2-month follow-up						Baseline to 6-month follow-up					
	<i>N</i>	Mean diff.	SD	95% CI	Effect size	In favor of SOF?	<i>N</i>	Mean diff.	SD	95% CI	Effect size	In favor of SOF?
MAIDS	15	-0.47	1.85	(-1.49, 0.56)	0.25	✗	14	-1.57	2.90	(-3.25, 0.1)	0.54	✗
Novaco anger raw score	13	6.46	14.63	(-2.38, 15.31)	0.44	✓	13	6.68	21.37	(-6.23, 19.60)	0.31	✓
Novaco provocation raw score	10	8.10	17.30	(-4.28, 20.48)	0.47	✓	10	7.60	14.26	(-2.60, 17.80)	0.53	✓
Glasgow depression score	12	2.42	5.79	(-1.26, 6.1)	0.42	✓	13	0.62	5.88	(-2.94, 4.17)	0.10	✓
Glasgow anxiety score	12	2.83	11.48	(-4.46, 10.13)	0.25	✓	14	1.64	12.33	(-5.48, 8.76)	0.13	✓
EQ-5D index	15	0.03	0.25	(-0.1, 0.17)	0.13	✗	14	0.09	0.32	(-0.09, 0.28)	0.29	✗
EQ-5D VAS	15	2.53	17.93	(-7.39, 12.46)	0.14	✗	14	0.50	16.07	(-8.78, 9.78)	0.03	✗
ICECAP-A	14	0.05	0.17	(-0.05, 0.15)	0.26	✗	14	0.01	0.10	(-0.04, 0.07)	0.15	✗
CHU-9D	6	0.029		(-0.03, 0.10)	0.045	✗	5	0.038		(-0.06, 0.14)	0.48	✗
MOAS	14	1.79	3.09	(0, 3.57)	0.58	✓	9	1.33	1.87	(-0.1, 2.77)	0.71	✓
Weighted MOAS	14	4.21	8.67	(-0.79, 9.22)	0.49	✓	9	3.33	6.48	(-1.65, 8.31)	0.51	✓
Glasgow depression proxy	6	-1.50	4.64	(-6.37, 3.37)	0.32	✗	3	-0.67	4.04	(-10.71, 9.37)	0.16	✗
ADAMS manic	13	0.54	3.41	(-1.52, 2.6)	0.16	✓	7	1.29	2.63	(-1.14, 3.72)	0.49	✓
ADAMS depressed	9	0.11	4.54	(-3.38, 3.6)	0.02	✓	6	-0.50	5.24	(-6, 5)	0.10	✗
ADAMS avoidance	12	0.67	3.52	(-1.57, 2.91)	0.19	✓	7	-0.57	3.55	(-3.86, 2.71)	0.16	✗
ADAMS anxiety	14	0.71	3.67	(-1.4, 2.83)	0.19	✓	6	1.33	4.46	(-3.34, 6.01)	0.30	✓
ADAMS obsessive	12	1.25	2.30	(-0.21, 2.71)	0.54	✓	6	0.50	1.05	(-0.6, 1.6)	0.48	✓
EQ-5D index proxy	14	0.08	0.29	(-0.09, 0.25)	0.27	✗	7	0.06	0.30	(-0.21, 0.34)	0.21	✗
EQ-5D VAS proxy	13	-2.08	21.00	(-14.77, 10.61)	0.10	✓	7	-8.29	17.41	(-24.39, 7.82)	0.48	✓
ICECAP-A proxy	13	0.03	0.17	(-0.07, 0.13)	0.19	✗	9	-0.001	0.15	(-0.11, 0.11)	0.01	✓
CHU-9D proxy	7	-0.03		(-0.12, 0.07)	0.24	✓	4	0.047		(-0.03, 0.012)	0.98	✗

The mean difference is denoted as baseline score minus follow-up time point. If this is negative, it denotes an increase in the score from baseline to the follow-up time point

intervention; these included the program manual, a mindfulness book, bean bags, and a tote storage bag at a total cost of £22.84 per therapist. Of the therapists trained in the study, ten therapists and one of the course trainers went on to deliver the intervention to nineteen individuals with ID and their carer, at a total cost of £46,085 for program delivery, equating to £2426 per participant. Sensitivity analysis which included the setup costs (training costs and course materials) attached to the therapists that delivered the intervention indicated that the program costs would rise to a total cost of £52,556 equating to £2766 per participant. The highest costs in the delivery of the program was the therapist time (including travel time) and costs associated with ongoing clinical and mindfulness supervision.

Service Use—Community-Based Services

Resource use data for the previous 4 months was obtained from 19 study participants at baseline and 14 participants post intervention (2 months following baseline) and at the final

follow up-at 6 months (post baseline). Table 5 below shows the summary of community-based contacts at baseline for the preceding 4 months. This table shows the breadth and frequency of contacts that this group of individuals are receiving across formal community services. For these 19 study participants, community services equated to a total mean cost of £1176 (SD 1786.77) per person (over the 4-month period prior to the start of the study). At the end of the intervention during the 2-month follow-up, excluding the cost of the UK SoF intervention, mean resource use costs for 14 participants was £1367.83 (SD 1710.79) for the preceding 4 months. At 6 months, the 10 participants followed up in the study showed they had received services with a mean cost per participant of £4063 (SD 7283.28). This was mainly made up of the costs of regular home help and family support worker visits. These data, however, are very skewed with a few participants receiving a great deal of input from these services and other participants none; they are reflected in the large standard deviation.

Table 5 Community-based service use in the last 4 months at baseline T0 (sample $n = 19$)

Service	Number of people	Unit cost	Total number of contacts	Mean (SD) number of contacts per user	Total cost £	Mean (SD) cost per person
Community psychiatrist	10	£341.36	19	1.9 (0.99)	£6486	£341 (410.26)
Psychologist	5	£62	10	2 (1.23)	£481	£25 (59.18)
General practitioner	5	£242	11	2.2 (1.10)	£1483	£78 (228.38)
Community psychiatric nurse	1	£39	1	1 (0)	£20	£1 (4.47)
Learning disability nurse	4	£44	19	1 (2.47)	£733	£39 (99.29)
Other community nurse	1	£42	2	2 (0)	£7	£0.37 (1.61)
Community mental health team member	0	£39	0	0 (0)	£0	£0 (0)
Healthcare assistant	0	£26.75	0	0 (0)	£0	£0 (0)
Speech and language therapist	0	£38	0	0 (0)	£0	£0 (0)
Physiotherapist	1	£38	1	1 (0)	£10	£1 (2.18)
Occupational therapist	0	£45	0	0 (0)	£0	£0 (0)
Art/drama/music therapist	1	£43	1	1 (0)	£215	£11 (49.32)
Alternative therapist	0	£43	0	0 (0)	£0	£0 (0)
Social worker/care manager	10	£82	23	2.3 (2.21)	£1378	£73 (104.65)
Social work assistant	0	£31	0	0 (0)	£0	£0 (0)
Home help/home care worker	3	£26	218	72.67 (57.98)	£6396	£337 (1076.12)
Advocate/counselor	2	£50	2	1 (0)	£100	£5 (15.77)
Dentist	8	£127	11	1.375 (1.06)	£516	£27 (47.44)
Optician	5	£31.44	12	2.4 (3.13)	£377	£20 (57.60)
Audiologist	0	£100.75	0	0 (0)	£0	£0 (0)
Chiroprapist	3	£38	9	3 (1)	£82	£4 (10.76)
Employment services/job center/work coach	1	£16.33	20	20 (0)	£163	£8.59 (37.46)
Family support worker	1	£54	12	12 (0)	£3888	£205 (891.97)
Dietician	0	£38	0	0 (0)	£0	£0 (0)
TOTAL	–	–	–	–	£22,335	£1176 (1786.77)
<i>Average per week</i>						<i>£67.82</i>

Service Use—Hospital-Based Services

The mean cost per person of hospital-based services used (for the previous 4 months at each time point) was £108 (SD 250.82) at baseline, £197 (SD 328.59) post intervention, and £52 (SD 108.78) at 6-month follow-up. Very few participants accessed hospital-based services; for example, only one participant attended A&E (at baseline), two participants had been to an outpatient appointment at the 6-month follow-up, and there were no overnight hospital stays at any time point.

Service Use—Psychotropic Medication Prescriptions

At baseline, analysis of psychotropic prescribed medication use showed that six of the 19 participants had received these drugs over the preceding 4 months at a mean cost per participant of £38.27 (SD 100.47, $n = 19$).

Service Use—Residential Setting and Additional Care Needs

More than half of the participants were resident in their family home or living in independent housing, with the remainder living in staffed group accommodation or sheltered housing. At the 6-month follow-up, we estimate that residential care services used over the preceding 4 months was at a mean cost per participant of £11,138 (SD 14491.63, $n = 10$).

Around half of the participants received informal unpaid care in addition to any formal paid care arrangements, with some participants receiving unpaid care from more than one person. At baseline, 45.46% of the unpaid carers ($n = 11$) had reduced their hours of work or given up work entirely to provide care for the individuals with ID in the study. Of those unpaid carers that had made changes to their working hours, 80% reported that this was due to the participants' anger

and aggression. At 6-month follow-up, five participants (of the 10 participants followed up) were receiving unpaid care from eight unpaid carers, of these, four unpaid carers had reduced their hours of paid work to provide care for the study participants, and in all cases, this was indicated as due to the participants' issues with anger and aggression.

Service Use—Participants' Contribution to the Workplace

At baseline, four (of the 19) study participants were in paid employment; in all cases, this was minimum wage or below and on a part-time basis. In addition, at baseline, three of the individuals with ID out of 19 had engaged in some voluntary work with the number of people volunteering rising to six (of the 10 followed up) at the 6-month follow-up time point.

Discussion

Recruitment rate was 90.5%, retention was found to be 73.7%, and adherence rate was 73.7%: all above the pre-set 50% criteria. Intervention fidelity scores were high, demonstrating that the manualized UK SoF intervention was implemented consistently across participants according to the manual. Although the effectiveness of the UK SoF intervention was not a primary aim, at 6-month follow-up, several outcomes showed improvement (anger and aggressive behavior, depression and anxiety). As additional information, the qualitative data from interviews with participants with ID, their carers, and the therapists can be found in Griffith et al. (2019).

Participant recruitment was somewhat determined by carer involvement. The need for a carer to support the individual with ID during the intervention was a prerequisite of the study and potentially excluded some participants who did not have the necessary carer support. Consideration could be given in future as to whether carer involvement is required for the intervention. The UK SoF intervention encouraged carers to engage in mindfulness practices alongside the participant so as to model the method and support the learning of the technique outside of the therapy sessions, similar in rationale to other studies (Jahoda et al. 2017). Retaining carers for both follow-up time points (2 and 6 months) was challenging, with only eight of a possible 14 completing study questionnaires at the 6-month time point (64%). Further consideration may need to be given to methods of retaining carers in the research.

A further recruitment issue was the number of people with ID who met study criteria but also had a diagnosis of ASD. Referrals into the study were limited by explicitly excluding this population. Additionally, despite the noted exclusion

criteria, those delivering the intervention reported that some participants exhibited features of ASD suggesting they may have some sub-threshold traits or an undiagnosed ASD (for example concrete thinking, repetitive speech, and need for routine). Future studies will need to consider the utility of excluding people with ID who have ASD, particularly when there is some evidence that the SoF technique can be successfully taught to adolescents with ID and ASD (Singh et al. 2011a).

A further aim of this study was to develop and test a mindfulness scale designed for individuals with ID. Based on participant responses and researcher feedback, the MAIDS was not found to be an appropriate measure. Participants found the concepts of mindfulness embedded in the questions difficult to understand. Rather than capturing the underlying mindfulness skill (awareness), the responses reflected a more literal understanding and possible acquiescence (Sigelman et al. 1981). Although this is disappointing, the results of this study illustrate that designing an appropriate questionnaire for mindfulness constructs for people with ID is challenging, particularly when aiming for a balance between comprehension and conceptualization. Future work in this area would benefit from user involvement in the development of such a measure.

If the UK SoF intervention was rolled out as part of normal service delivery, then initial setup costs could be annuitized across a number of years; furthermore, increasing the number of courses each therapist delivered would also result in a reduced cost per participant. It could also be argued that if rolled out into routine care, many of the intervention costs observed as part of the feasibility trial would be absorbed into existing service delivery budgets rather than placing an additional burden on already under-resourced services. The previous cost-benefit research from the United States (Singh et al. 2008a) excluded setup costs on the assumption that the cost of the additional staff training was identical to other behavior management training.

Further economic evaluation of the UK SoF intervention should include a control group so that the incremental intervention costs could be calculated and a budget impact analysis conducted to assess the likely costs of roll of nationally. At this feasibility stage, we were able to show that it was possible to demonstrate the breadth and frequency of contacts across community and hospital-based services and to record prescribing of drugs relevant to anger management. We showed that support workers and family support were able to provide information about living circumstances, paid work, and other daytime activities relating to study participants. There were missing resource data, and we would suggest using a shortened resource use questionnaire, and a mixed methods data collection approach would be useful, focusing on what has changed since the last point of data collection to capture a full representative picture of service use and associated costs.

Limitations and Future Research

Retaining carers in the study proved challenging as noted earlier, as did the exclusion of participants with ID and ASD. The development of an appropriate mindfulness measure also proved difficult. It is suggested that any future research protocol should consider these issues. As this was a feasibility study, testing the effectiveness of the UK SoF intervention was not a primary aim (Bowen et al. 2009); although, there was evidence to suggest that there were reductions in reported anger and aggression in both the quantitative and the qualitative data (Griffith et al. 2019). Based on the feasibility outcomes of this study and the number of suggested adaptations to the protocol, it would seem sensible for future research to conduct a pilot clinical trial rather than developing a full RCT at this stage.

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Compliance with Ethical Standards

Conflict of Interest All authors declare that they have no conflict of interest.

Ethical Statement This study was approved by the research ethics committee at the School of Psychology, Bangor University and the NHS ethics committee (REC 5; 15/WA/0213).

Informed Consent Statement Informed consent was obtained from all individual participants included in this study.

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