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STUDY PROTOCOL

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A randomised controlled feasibility trial for an educational school-based mental health intervention: study protocol

Katharine Elizabeth Chisholm^{1*}, Paul Patterson², Carole Torgerson³, Erin Turner⁴ and Max Birchwood¹

Abstract

Background: With the burden of mental illness estimated to be costing the English economy alone around £22.5 billion a year [1], coupled with growing evidence that many mental disorders have their origins in adolescence, there is increasing pressure for schools to address the emotional well-being of their students, alongside the stigma and discrimination of mental illness. A number of prior educational interventions have been developed and evaluated for this purpose, but inconsistency of findings, reporting standards, and methodologies have led the majority of reviewers to conclude that the evidence for the efficacy of these programmes remains inconclusive.

Methods/Design: A cluster randomised controlled trial design has been employed to enable a feasibility study of 'SchoolSpace', an intervention in 7 UK secondary schools addressing stigma of mental illness, mental health literacy, and promotion of mental health. A central aspect of the intervention involves students in the experimental condition interacting with a young person with lived experience of mental illness, a stigma reducing technique designed to facilitate students' engagement in the project. The primary outcome is the level of stigma related to mental illness. Secondary outcomes include mental health literacy, resilience to mental illness, and emotional well-being. Outcomes will be measured pre and post intervention, as well as at 6 month follow-up.

Discussion: The proposed intervention presents the potential for increased engagement due to its combination of education and contact with a young person with lived experience of mental illness. Contact as a technique to reduce discrimination has been evaluated previously in research with adults, but has been employed in only a minority of research trials investigating the impact on youth. Prior to this study, the effect of contact on mental health literacy, resilience, and emotional well-being has not been evaluated to the authors' knowledge. If efficacious the intervention could provide a reliable and cost-effective method to reduce stigma in young people, whilst increasing mental health literacy, and emotional well-being.

Trial registration: ISRCTN: ISRCTN07406026

Keywords: Adolescence, Mental health, Stigma, Contact, School, Intervention

Background

There is growing pressure on schools in England to address stigma and misconceptions of mental illness [2-5] as well as increasing emotional well-being [6,7] in addition to traditional academic curricula. Currently there is little agreement as to what approach might most successfully address these issues [9-11].

Over half of all lifetime mental disorders have their onset during childhood and adolescence [12] yet young people's knowledge of mental illness is often incomplete [13] or influenced by sensationalised reports in the media [14]. Developmentally, adolescence is a complex period, with the majority of young people experiencing some level of distress or emotional problems. The adolescent brain has been shown to confer higher risk for mental illness due to a difference in the maturation of the developing brain and the adolescent emotional and cognitive systems [15]. Adolescents also experience high levels of

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schizotypal thinking [16], something which among adults is related to high vulnerability to mental illness [17].

Individuals with mental illness experience discriminatory attitudes in almost all areas of their lives [18,19], and stigma, alongside poor mental health literacy, can increase barriers to help-seeking [20,21]. Prevalence rates for psychotic disorders such as schizophrenia increase rapidly between the ages of 15 to 17 [12] with children and adolescents who experience early onset anxiety disorders such as phobias and separation anxiety disorder more likely to develop co-morbid disorders of substance use, later-onset anxiety, or mood [12]. Earlier age of onset for many mental illnesses is also correlated with greater severity [22], persistence [23] and increased resistance to treatment [24].

Young people themselves report that they would like to receive more information regarding mental health. Both Kidger et al. [25] and Woolfson et al. [26] found that students stated that they were dissatisfied with the mental health education they were receiving. Olsson and Kennedy [13] found that less than 30% of students recalled any discussion of mental health during school lessons, despite the fact that mental health education was mandatory in the area their research was conducted.

There is growing evidence to suggest that early interventions designed to optimise well-being or reduce mental illness and initiated during childhood and adolescence may help reduce mental health problems in later life [27-29]. The UK National Healthy Schools Programme attempts to address this, and advocates increasing emotional health and well-being (EHWB) support for students [30]. Schools engaged in this programme are expected to address subjects related to social skills and emotional health to their curriculum with targets including 'combating stigma and discrimination'; and 'encouraging the participation of children and young people in activities designed to build their confidence and self esteem' to achieve National Healthy Schools Status. There is however, no obligation for schools to take part and some remain uninvolved. Additionally, with lack of monitoring and threat of further funding cuts, the current programme appears vulnerable.

Previous interventions

Reducing stigma and discrimination of mental illness, improving mental health literacy, reducing a particular mental illness, or promoting resilience are all popular methods for tackling mental health issues in schools [31-40]. Such interventions often demonstrate significant benefits such as reducing stigma, conduct problems and increasing prosocial behaviour [41], challenging negative opinions of psychosis [42], and can have a positive impact on interrelated factors such as school achievement, school climate, and reduced emotional behavioural and

disciplinary problems [43-45]. The abundance of interventions are however, not easily comparable, and identifying which components of an intervention are successful, and which components lack utility, is often not possible. This has led to some large-scale interventions being instigated without a clear understanding of the likely efficacy of trial components. For example the *BeyondBlue* [46] trial in Australia included 50 schools in a five year intervention aimed at reducing and preventing depression and reported flat results [47]. Feasibility trialling and careful evaluation is needed to capture the potential problems as well as benefits of school interventions prior to the widespread dissemination of larger scale projects [9,48,49].

Many systematic reviews now concur that whole school approaches are the most effective model and emphasise the need to promote mental health universally rather than solely targeting the reduction of mental illness [11,50,51]. A greater investment in long-term approaches are also favoured by reviewers [11,52] and it has been suggested that future research should include more detailed analysis of demographic variables such as ethnicity and gender [9].

Regarding stigma and mental health literacy, fewer systematic reviews have been conducted into school-based studies. Kelly et al.'s [21] review concluded that for adolescents, good mental health literacy is associated with more positive outcomes for emotional well-being but add a caveat that very few school interventions to improve mental health literacy have been evaluated and even fewer *well* evaluated. Pinfold et al.'s [53] systematic review suggested that contact with individuals who describe personal experience of mental illness was more likely to lead to reductions in reported stigma; in contrast, a systematic review by Schachter et al. [48] failed to find any 'even remotely ideal investigation[s] whose results regarding possible benefits we can confidently accept as being reliable and valid' (p. 22). Schachter et al. criticised studies for a range of reasons including; inadequate study descriptions; poor research methodology; inadequate interventions; and failing to measure or control for relevant baseline characteristics of participants. Funding is also an issue in the present climate, with programmes designed to impact upon mental health issues in schools needing to demonstrate value for money as well as reliable and consistent effect sizes [9,54]. In summary, further well-designed research in these fields is warranted.

Contact and stigma

Corrigan et al. [55] identify three strategies for challenging stigmatising attitudes and prejudice towards mental illness: 'protest', 'education', and 'contact'. 'Protest' involves condemning prejudicial attitudes; if a company

were employing an advertising campaign that was deemed to be stigmatising, public protest may encourage changing of the advert, thus suppressing the stigmatising attitude. 'Education' seeks to encourage an increase in knowledge and awareness regarding mental illness, thereby dispelling myths in the belief that the more individuals understand the less prejudiced they will be. 'Contact' reasons that the more contact an individual has with someone who has experienced mental illness, the less stigmatising they will be, although the relationship is correlational - it may equally be the case that those who hold less stigmatising attitudes towards mental illness are happier to have contact with individuals experiencing mental illness [55]. Rusch et al. [56] note that if contact is employed to facilitate attitude change then this must be carried out under a controlled set of circumstances if the best possible outcome is to be achieved, otherwise the intervention may have a negative rather than positive outcome. Allport [57] who first proposed the contact hypothesis, similarly claimed that contact needed to involve individuals of equal status with the 'in' and 'out' groups working together rather than in competition with one another. Of protest, education, and contact, Corrigan et al. argue that contact is the most effective, followed by education, with protest having little significant impact on participants. Like Minds [19] add that contact married to education is a powerful combination for combating stigma.

Contact has been employed as a strategy to reduce stigma and increase understanding of mental health issues in a number of studies with adults [55,58] but rarely in school interventions [53,56]. Results have however shown promise, and contact may be a way of increasing the impact of interventions by facilitating engagement and overcoming barriers to learning. To date, contact has not been utilised to improve mental health literacy and emotional well-being in young people, but there is some evidence to suggest that it might have a favourable effect as two recent qualitative studies have indicated that young people wish to be taught about emotional well-being and mental health issues by someone who has lived experience of mental illness [25,26].

The current study

The SchoolSpace intervention programme has been designed to measure the impact of an educational intervention on three core targets: reduction in stigma related to mental illness; mental health literacy; and promotion of mental health, with reduction in stigma related to mental illness being the primary outcome. Previous research has suggested that these may be interlinked [41]. For example, someone who doesn't *understand*, or is *prejudiced* against mental illness, may not seek help

[20,21], leading them to be less *resilient*. The primary research question asks; 'is education in combination with contact better than education alone for reducing stigma?' Based on previous research [26,53] it is hypothesised that participants in the contact and education condition will report significantly reduced stigma towards mental illness compared with participants in the education only (control) condition.

Secondary research questions relate to how contact in combination with education may influence participants' a) mental health literacy, and b) emotional well-being and resilience, compared to education alone. In addition to this the trial will assess any influence of contact on attitudes to help-seeking. Previous research has found that stigma is a major barrier to help-seeking [20], and that low mental health literacy can lead to a delay in help-seeking [34]. It is therefore hypothesised that a reduction in stigma and increased mental health literacy will be associated with an increase in positive attitudes towards help-seeking.

Additionally, schizotypal thinking, which is linked to vulnerability to mental illness [17] and is common during adolescence [16] will also be measured. This addresses whether higher rates of schizotypal thinking in adolescence are linked to adolescents' increased vulnerability to developing mental illness compared to other age groups, or if such thinking patterns are developmental in some way [59]. If they are a sign of an adolescents increased vulnerability to mental illness then with increased resilience and increased mental health and emotional well-being, we hypothesise that rates of schizotypal thinking should reduce in participants. However, if schizotypal thinking is developmental then we might expect to see the opposite trend, with schizotypal thinking unaffected by any changes in mental well-being or resilience.

Method/Design

SchoolSpace is a randomised controlled trial with two conditions: an experimental condition which includes contact with a young person with lived experience of mental illness as well as education, and an active control condition, which includes education but no contact. Measures will be taken 3 weeks prior to the intervention, and at both 2 weeks and 6 months post intervention. Random allocation will take place at the level of school and blocking will be used to randomly stratify classes to different conditions. Random allocation will be independent and concealed. Randomisation will be undertaken by an individual independent of the research team, and will take place after pre-test. The intervention has been designed in accordance with CONSORT guidelines [60,61].

Participants

7 schools will take part in the intervention, with students aged 12-13. Schools will be chosen to represent a cross section of demographics, including different ethnic groups and genders. The average year group within Birmingham secondary schools takes approximately 150 students enabling up to 1050 participants in this feasibility trial.

Ethical approval

The study was granted ethical approval by The University of Birmingham ethics committee in June 2010 (reference number ERN_10-0397), and the primary author is funded through the NIHR CLAHRC (Collaborations for Leadership in Applied Health Research and Care) Birmingham & Black Country programme.

Development and piloting of the intervention

Original intervention materials were developed by K.C., E.T. and P.P. in collaboration with teachers and service-users with additional educational resources evolved from the work of Dr Gary O'Reilly [62] and the Staffordshire Changes YP mental health programme [63]. Focus groups were also conducted with young people by K.C. to aid the development of the programme. Interventions tend to be more successful if they are delivered over time, rather than in one intensive session [9], however the current intervention is a feasibility trial, and due to the constraints of resources, it was decided that a one-day intervention would be used, with the expectation that the intervention will be developed into a longer term intervention plan for evaluation in the future, should it prove to be successful.

The intervention was piloted in one school to assess the practicality; timings, level of pitch, and suitability of materials for the target age group. Classes were randomised to the Education and Contact condition and Education Only conditions. Procedure of the pilot intervention is identical to the feasibility trial.

Feasibility trial

The feasibility trial intervention covers three interrelated subjects; 1. Stigma of mental illness, 2. Mental health literacy, and 3. Improving our own mental health. Pupils receive four hours aimed to impact upon the former two of these subjects and two hours aimed to impact upon the latter. In the education and contact condition a young person with experience living with mental illness will work with the students as one of the teaching assistants and will lead a 10-20 minute presentation and interactive discussion about living with a mental illness.

The intervention will be delivered by NHS mental health specialist staff and service-users. Training and workshop notes are provided for all individuals prior to

their facilitating the interventions to ensure fidelity of implementation. The intervention will be delivered to students in their normal class size and environment.

Procedure

Stage 1; consent and pre-test

Schools in the Birmingham area will be approached and invited to take part in the research, drawn from the full range of socio-economic and socio-cultural settings. Once a school has agreed to participate, consent letters will be sent out to the parents of all participating students.

Pre-intervention questionnaires will be completed 3-4 weeks prior to the intervention day. A self-generated code will be used to match participant answers over time whilst preserving anonymity. This code has a reported 92% success rate [64]. It must therefore be expected that a minimum of 8% of participants may be lost over time due to mistakes in the generation of this code. Teachers will have over a week to collect questionnaire data in order to minimise loss of data through student absences from school.

Class randomisation to condition will take place after pre-test, at the level of school.

Stage 2; the intervention

Participants are taught within their usual classes. Each class is facilitated by 2-4 staff including a lead who will be a NHS mental health specialist, and a teaching assistant. Facilitators in the education and contact condition include at least one facilitator who has lived experience of mental illness. As well as the facilitators a minimum of one teacher from the school will be present in each class. Fidelity of the intervention delivery between conditions will be assessed with a pre-developed checklist on the intervention day. One class per condition, per school will be assessed for fidelity by K.C.

Stage 3; post-tests

Approximately 2 weeks after the intervention day post-intervention questionnaires will be completed by participants, and then again at 6 month follow up.

Primary outcome measure

Stigma of mental illness

The Reported & Intended Behaviour Scale (RIBS) [65] assesses behaviour related to the stigma of mental illness. The RIBS takes around 1-2 minutes to complete and rates participants' willingness to have contact with individuals who are experiencing mental illness (e.g. 'In the future I would be willing to live with someone with a mental health problem'), as well as their current and past experiences (e.g. 'Are you currently living with, or have you ever lived with, someone with a mental health problem?'), though only the former questions generates the participants final score. The RIBS has a test-retest reliability of

0.75, and Cronbach's alpha for items 5-8 (those which generate the participants final score) is 0.85.

Secondary outcome measures

Knowledge of mental illness

Knowledge of mental illness will be assessed in two ways. The Mental Health Knowledge Scale (MAKS) [66] assesses six areas of stigma-related knowledge: help-seeking, recognition, support, employment, treatment, and recovery, takes 1-2 minutes to complete and has a test-retest reliability of 0.71.

Two vignettes will be employed to assess knowledge of mental illness developed by Jorm et al. [67].

Emotional well-being

The Strengths and Difficulties Scale (SDQ) [68] will be used to assess the emotional well-being and consists of 25 items which generate scores along five subscales: conduct problems, hyperactivity-inattention, emotional symptoms, peer problems, and pro-social behaviour, as well as producing a total difficulties score. The SDQ has been validated for use with adolescents age 11-16 with a Cronbach's alpha of 0.82 for the total difficulties scale [68].

Resilience

Resilience will be measured using a 15 item [69] version of Wagnild and Young's [70] Resilience Scale (Cronbach's alpha of between 0.72-0.94) [71] and concurrent validity is supported by correlations between the Resilience scale and measures of depression, morale, and life satisfaction. The Resilience scale has been used previously in three studies with adolescents [72-74].

Help-seeking

Attitudes to help-seeking will be assessed by responses to the question 'In the next 12 months if you were to experience a mental illness, how likely are you to seek help?'

Exploratory outcome measure

Schizotypal thinking

The Schizotypal Personality-Brief Form (SPQ) [75,76] assesses three subscales relating to schizotypal thinking; cognitive-perceptual deficits, interpersonal deficits, and disorganisation. It takes approximately 2 minutes to complete and has an internal reliability of 0.76, a test-retest reliability of 0.90, and has been validated for use with adolescents [77].

Power and sample size calculation

Assuming an intra-cluster correlation coefficient (ICC) of 0.037 [78] (Aberdeen University: Health Services Research Unit) and a cluster size of approximately 30 students per class, 738 participants would be needed to detect a 0.3 effect size, or 1658 participants to detect a 0.2 effect size. Depending on the size of the included

schools, the proposed research will allow for detection of an effect size between 0.3-0.2.

Analysis

Data will be analysed applying appropriate general linear models. In order that the clustering of the sample does not bias the analysis pre-test outcome measures will be entered as a covariate. Subgroup analyses will look at gender, ethnicity, religion, and mental health status of self, family, and friends in relation to the hypotheses and data analysed using appropriate general linear models. Intention to treat analyses will be used.

Discussion

The strengths of the proposed research are both in its potential for increasing efficacy by the use of contact combined with education to combat primarily stigma, and also in improving mental health literacy and resilience/well-being. Previous research suggests that the intervention may have some effect on stigma even at 6-month follow up, due to this influence of contact combined with education. Pinfold et al. [79] for example, employed contact with an individual with personal experience of living with mental illness in their intervention with 14-15 year old students. Although their intervention was brief, lasting for just two one-hour workshops, a significant positive change in stigmatising attitudes was found both immediately following the intervention and also at 6-month follow up.

Previous interventions have tended to focus on one or at most two of the concepts of stigma, mental health literacy, and resilience/well-being, rather than all three [35-40,42]. This is despite evidence inferring that the three concepts are to some extent interlinked [20,21]. For example, Naylor et al.'s [41] intervention significantly reduced conduct problems and improved prosocial behaviour, despite the fact that the intervention did not contain any features designed to reduce mental illness or promote mental health. Though the research is not directly designed to look at this, if stigma, mental health literacy, and resilience/well-being are interlinked, it may be that by addressing all three simultaneously, a greater impact can be achieved.

The current intervention also addresses many of the methodological issues which have been highlighted by previous systematic research reviews as problematic [9,48]. The study has a high level of power; utilises an active control group; measures and evaluates demographic differences including ethnicity, religion, and gender for response to the intervention; attempts to improve consent rate by utilising an opt-out consent method; is delivered by the research team rather than by teachers from the individual schools and assessed for fidelity of implementation. The research measures mediator variables such as resilience as well as baseline characteristics

of the individual such as whether they know someone with a mental illness, and the exact nature and content of the intervention will be explicitly described and freely available.

If positive trends result from the present feasibility trial this will support the development of further longitudinal work on a larger scale, something which is urgently needed in this field.

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Authors' contributions

KC is chief investigator on the project and drafted the manuscript. KC, PP, and ET contributed to the development and implementation of the intervention. MB, PP, and ET supervise KC. All authors contributed to the design of the study. All authors contributed to the editing of the manuscript and have read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

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