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Protocol: A brief intervention targeting anhedonia in adolescents: a feasibility randomised controlled trial

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Background:

Depression is a common mental health problem (NICE, 2009) and a worldwide leading cause of disability (WHO, 2020). Major depressive disorder (MDD) often begins during adolescence, with up to 20% of young people experiencing a depressive episode by the age of 18 (Thpar, Collinshaw, Pine & Thpar, 2012). Adolescent-onset MDD is associated with recurrent episodes and an increased risk of chronicity (Richards, 2011). Adolescent depression is also associated with social dysfunction, academic difficulties (Fombonne, Wostear, Cooper, Harrington, & Rutter, 2001) and if untreated, the development of other serious disorders (de Girolmi et al., 2012). However, current treatments of adolescent depression are suboptimal (Lewandowski et al., 2013), and difficult to access (Health Committee, House of Commons, 2014).

Current treatments of (adult) depression may be only partially effective because there is more emphasis on reducing (or down-regulating) the negative affective experience of depression (Dunn, 2012), rather than building (or up-regulating) the positive affective experience. According to the DSM-5 (APA, 2015), the two symptoms required for a diagnosis of depression are either: 1) persistent depressive mood (including irritability for adolescents) or 2) markedly diminished interest or pleasure in all or most activities (anhedonia). These symptoms are thought to demonstrate "disruptions to two underlying and partly dissociable neurobiological dimensions of depression" (Dunn et al., 2019, P1) (Carver & White, 1994; Gray, 1987; Insel et al., 2010; Paulus et al., 2017; Watson, Wiese, Vaidya, & Tellegen, 1999) that reflect the two core cognitive-affective systems that regulate thoughts, feelings and behaviours (Craske, Meuret, Ritz, Treanor & Dour, 2015; Dunn, 2012); the positive valence system (PVS) and the negative valence system (NVS). Down-regulation of the PVS reduces positive affect and up-regulation of the NVS increases negative affect (Dunn et al., 2019). Craske et al., (2019) posit that positive valence is associated with the approach/appetitive system which motivates individuals to work towards goals/rewards and generates positive emotions; and negative valence is associated with the withdrawal/defensive system which motivates individuals to avoid aversive outcomes and produces negative emotions, such as anxiety and depression. Deficits in the PVS/appetitive system are described as the loss of enjoyment or desire to engage in pleasurable activities (anhedonia) (Craske et al., 2015, Craske et al., 2019). However, despite the fundamental role played by the PVS/appetitive system and NVS/defensive systems in depression, evidence-based psychological therapies, including cognitive behavioural therapy (CBT) and mindfulness-based cognitive therapy, do not significantly target or change positive affect (Boumparis, Karyotaki, Kleiboer, Hofmann & Herman-Dunn, 2016). Even behavioural activation which aims to increase positive affect by encouraging individuals to re-engage with potentially rewarding activities has limited effects on anhedonia (Moore et al., 2013), because there is little

evidence on how to help depressed individuals gain enjoyment from these activities (Werner-Seidler et al., 2012). Finally, pharmacological treatments of depression also struggle to treat anhedonia, with standard medication treatments having little effect or even worsening anhedonia (Price & Goodwin, 2009).

One third of individuals with depression have clinically significant anhedonia (lack of positive affect) (Pelizza & Ferrari, 2009), and anhedonia predicts acute symptom severity, a chronic, relapsing future course, poor treatment response, and is a marker of risk for suicidality (Dunn et al., 2019; Morris, Bylsma & Rottenberg, 2009; Ducasse et al., 2018; Winer et al., 2014). Restoration of positive mood should therefore be a primary treatment goal of depressed patients (Demyttenaere et al. 2015). Treatments are now emerging in adult populations that target the underlying cognitive mechanisms that impair the PVS and reduce positive affect.

Whilst these studies suggest promising treatments for upregulating positive affect in adults, to our knowledge, there are no such treatments available for adolescents with anhedonia. This is problematic because in the UK, 50-78% of young people with MDD report experiencing anhedonia (Orchard, Pass, Marshall & Reynolds, 2016; Goodyer et al., 2017). Furthermore, in adolescents, anhedonia is a greater predictor of poor treatment outcomes than other symptoms of depression and may be a key factor in adolescent suicidality. Despite promising initial findings from these treatments in adults, it cannot be assumed that identical effects will be found in adolescents because this is a time of rapid emotional and cognitive development, including the strengthening of 'top-down' cognitive control, goal-directed behaviour, working memory and attention allocation (Yilmaz et al., 2019; Beatriz et al., 2013). For example, whilst the use of dampening appraisal appears to be a maintenance factor of anhedonia in adolescents, the effects are said to be smaller than in adults (Yilmaz et al., 2019). Furthermore, these interventions, like much of traditional cognitive therapy, use verbal processing approaches. However, imagery-techniques may be more developmentally appropriate for adolescents (Pile et al., 2018). There is increasing evidence that mental imagery may target currently neglected but potentially beneficial cognitive processes in treating depression. For example, harnessing positive imagery rather than verbal thoughts, may have a greater impact on positive affect (Boland et al., 2018; Holmes et al., 2016). Lastly, these interventions targeting anhedonia in adults are lengthy (>8 sessions), making them more expensive and less accessible.

Mental images are characterised as 'seeing with the mind's eye' and unlike verbal thoughts are considered to have close access to sensory information (Kosslyn, Ganis & Thompson, 2001). Mental images can be positive or negative and vary from being deliberately brought to mind (i.e. planning

future events) to intrusive and distressing (Holmes & Matthews, 2010). In adults, depression and anxiety are associated with increased predictions of negative future events, however a deficit in generating positive future imagery is only associated with depression (Holmes, Lang, Moulds & Steele, 2008; Holmes et al., 2016; Strober, 2000; MacLeod & Byrne, 1996). The ability to vividly generate mental images of future events may underlie an individual's ability to make positive predictions about the future (including forming detailed and specific plans) (Boland, Riggs & Anderson, 2018). This is important because whilst depressed individuals, compared to non-depressed individuals, report similar numbers of future goals and similar importance of these goals, they predict these goals are less likely to occur and that they have less control over them (Dickson, Moberley & Kinderman, 2011). Furthermore, depressed individuals find it easier to disengage from unobtainable goals and report more difficulty in engaging with new goals (Dickson, Moberley, O'Dea & Field, 2016). Therefore, biased predictions about future events may occur because depressed individuals have difficulty generating vivid images of specific future events, as over-general future thinking has been evidenced in both depressive and dysphoric individuals (Anderson, Boland & Garner, 2016; Dickson & Bates, 2006; Williams et al., 1996). Similar results have been found in adolescents, whereby less vivid positive mental images and greater vividness of negative images are associated with symptoms of depression Pile and Lau (2018). Diminished perceptions of control over life events are closely linked with feelings of helplessness and pessimistic future expectancies, which are characteristic of MDD and suicidality. Positively, results from Boland, Riggs & Anderson, (2018)'s experimental study showed that after simulating positive future events, participants were reported these events were more vivid, likely to occur, controllable and important. This suggests that engaging in positive future imagery may increase motivation to achieve goals. Additionally, the ability to engage positive future mental imagery is positively associated with optimism (largely characterised as positive expectations of the future), which is strongly linked to psychological wellbeing and resilience to stress (Blackwell et al., 2013; Ji et al., 2017). Positive future imagery may also promote positive affect following a negative life event (Pile & Lau, 2018), as findings from experimental studies in adults show that engaging in positive imagery not only improves mood and positive interpretation bias, but also protects against negative mood inductions (Holmes et al., 2009), and in adolescents, vividness of positive future events moderates the relationship between negative life events and depression (Pile & Lau, 2018). These findings are particularly relevant given the current coronavirus pandemic (COVID-19) and highlight the importance of positive prospective imagery in the treatment of adolescent depression.

IMAGINE-POSITIVE (IMAGINE-P) is a novel and brief (4 sessions) school-based intervention for adolescent depression (Pile et al., 2018) that aims to increase access to early support and target the

underlying mechanisms of adolescent depression, using techniques of memory specificity and imagery re-scripting for negative events but also to bolster clear mental images of positive events. Initial findings from their case series (Pile et al., 2020) and feasibility RCT (Pile et al., 2021*)* suggest that imagery-based cognitive approaches are feasible for use with adolescents, improve mood and self-esteem, and are acceptable to young people. By adapting IMAGINE (Pile et al. (2018; 2020) and incorporating elements of other positive affect interventions, we have developed a novel and brief intervention for anhedonia in adolescent depression which aims to increase positive affect. Positive mental imagery is used to shift attention to positive affect (generating and savouring positive future goals and enhancing self-compassion) and manage the dampening appraisals which reduce positive affect (i.e. dampening appraisals).

Aims:

The primary aim of IMAGINE-P (Integrating Memories And Generating Images of New Experiences-Positive) is to develop a brief school-based intervention for young people that harnesses the ability to imagine positive future events in order to reduce anhedonia (improving positive affect) and to assess this for feasibility and acceptability. This structured intervention will be delivered face-to-face by a practitioner without extensive psychological training. A secondary aim will be to measure emotion regulation strategies deployed by young people to maintain positive affect during a universal stressor: the COVID19 pandemic. The project is a case series and feasibility randomised controlled trial (RCT) to refine the intervention manual and assess feasibility and acceptability. The RCT will also inform on whether a full-scale efficacy trial is warranted and will provide initial estimates of effect sizes.

Primary aims:

1. To develop a therapy manual that is brief, easy-to-access and appropriate to deliver online by a practitioner without extensive training. Development of the therapy manual includes a systematic review of the current treatments of anhedonia in depressed adult populations, as well as conducting a case series.
2. To run a feasibility RCT to evaluate recruitment and retention rates for a future efficacy RCT, for example recruitment rates for schools and participants, attrition rates and outcome measure completion.
3. To assess the acceptability of the intervention to participants using post-therapy feedback questionnaires.

Secondary aims:

1. To gather descriptive data on symptom-change to inform sample size estimates for a future fully powered RCT of clinical and cost-effectiveness.
2. The secondary aim is to collect pilot data on clinical measures as well as on the underlying mechanisms proposed to be targeted in the intervention. This will include measures of imagery vividness, emotional response to positive future imagery and memory specificity.

Methods/ designs

Study design and timeline

In the case series all participants will receive the intervention. Participants will be recruited from multiple school/ college sites in the United Kingdom. Participants will be assessed at pre-intervention (prior to randomisation) and at follow-up, after the intervention, and at a 3-month follow-up after the intervention. For the feasibility randomised controlled trial, participants will be randomly allocated to either the intervention group or a control group (non-directive supportive therapy). Both of these are active interventions that aim to improve mood and self-esteem. Participants will also be recruited from multiple school/ college sites in the United Kingdom. Participants will be assessed at pre-intervention (prior to randomisation) and at follow-up, after the intervention, and at a 3-month follow-up after the intervention.

Study population

Inclusion criteria

1. Aged 14-19
2. Informed consent
3. Willing and able to engage in psychological therapy and complete assessments
4. Scoring above clinical cut-off on the MFQ (29 items; clinical cut-off ≥17), and showing high symptoms of anhedonia, as measured by the SHAPS (14 items; abnormal level of hedonic tone >2)

Exclusion criteria

1. Diagnosis of learning disability (but not difficulty e.g. dyslexia), diagnosis of Autism Spectrum Disorder, or significant head injury, neurological disorder or epilepsy
2. Unable to fluently communicate in spoken English

3. Unable to give informed consent
4. High levels of current risk
5. Currently receiving therapy (including school counselling)
6. Experiencing psychotic symptoms or depressed in the postnatal period (participants with co-morbid physical illness or non-psychotic disorders such as anxiety will not be excluded)

Setting

The intervention will be delivered face-to-face. The practitioner delivering the intervention will be working from a private workspace and participants will receive the intervention at school in a private designated space. Participants will complete their screen and assessment questionnaires online using Qualtrics.

Sample size

For the case series, 10 participants will be recruited. As the purpose of the trial is to assess feasibility and not efficacy, a power calculation to determine sample size is not appropriate. The data from this trial could however be used to inform a sample size calculation for a future efficacy trial. The target sample size (n=32; 16 in each arm) was determined with reference to good practice recommendations for feasibility/ pilot studies, which recommend sample sizes of between 24 and 50 (Julious, 2005; Lancaster, Dodd, & Williamson, 2004; Sim & Lewis, 2012). The sample size of 50 was inflated to allow for drop-out following randomisation, which was estimated to be 10% based on similar studies (Smith et al., 2015).

Recruitment (case series and trial), randomisation and blinding (trial only)

All participants will be recruited from a secondary school or sixth form college. The project researcher will liaise with the school gatekeeper and present the study to all students aged 16 to 18. All students will be provided with an information sheet at least 24 hours before the presentation to consider taking part. Following the presentation, all students will be invited to complete the screen questionnaire online if they wish to do so. At the screening stage we will ask the students' consent to inform the pastoral lead/ gatekeeper of their interest in the study, to ensure there is a private space at school for them to complete their sessions. Following the screen, eligible participants will be identified by scoring above clinical cut-off on the Mood and Feelings Questionnaire (MFQ) and showing high symptoms of anhedonia on the Snaith Hamilton Pleasure Scale (SHAPS). At the first assessment, the MFQ and SHAPS will be administered again, and participants will be assessed against the eligibility criteria. As participants will be over the age of 16, we will not seek parental

consent, but we will follow each school's recommendations on contacting parents and discussion of their child's interest in participation. This may be done via telephone, email or letter and may involve providing parents with information about the trial and giving them the opportunity to contact the research team if they would like to discuss the study further.

For the trial only, following the assessment, participants will be randomly allocated to either the intervention group or the control group. Due to the nature of the intervention, a double-blind design is not possible as the young person will be aware of which intervention they are receiving and the practitioner will be aware of which intervention they will be delivering. However, as both are active therapeutic interventions, this should minimise any potential bias associated with expectations of the intervention benefits. The experimental and control interventions will be referred to as intervention 1 and intervention 2, and both will be described as 'programmes aiming to improve low mood and self-esteem' in all participant and staff literature in order to promote equal intervention credibility between the conditions. Thus, participants will not be informed which is the 'new' intervention to avoid potential disparities in expectancy. All reasonable attempts will be made to keep school staff blind as to which intervention.

TH will be primarily responsible for gathering the data and will deliver both therapeutic interventions. Assessments will be completed by a trained individual independent from the clinical research team (e.g., research assistants and doctoral students), who will be blind to the intervention allocation. Participants who drop out or discontinue the intervention will still be invited to complete the assessment sessions. Good Clinical Practice guidelines for clinical trials will be followed.

Interventions

Experimental intervention: IMAGINE-POSITIVE (IMAGINE-P)

The intervention will combine aspects of Memory Specificity Training (MeST), to educate on the links between memories and emotions, with Positive Prospective Mental Imagery (PPMI), to increase vividness and savouring of positive future images in order to harness positive affect. PPMI will first be introduced with a short-term goal that the participant wishes to complete in the next seven days. Participants will be guided to build up a detailed image of this goal, helping to increase imagery vividness, and are encouraged to engage in savouring techniques to bolster positive affect during the imagery generation. Dampening thoughts that may interfere with the image and reduce positive affect are identified. The role of self-critical thoughts are also explained and an imagery-based exercise for self-compassion is practiced. Participants then engage in PPMI for more long-term goals

to help identify practical steps towards their goals and anticipate any challenges or strengths along the way to achieving those goals. Lastly, participants link their specific memories and positive future images to their values.

Control intervention

Non-directive supportive therapy (NDST) will be delivered to participants in the control group, as it is a NICE recommended treatment for mild depression (NICE, 2019). NDST consists of individual sessions, whereby the practitioner is empathetic, emotionally supportive and provides non-directive problem solving and monitoring. Using NDST will control for factors that may contribute to change, which are not active components of IBCI-PA e.g. speaking to an empathetic therapist. Initial findings from a school-based feasibility RCT using NDST as the control intervention (Pile et al., 2020), found that NDST improved mood, suggesting it is more ethical for randomization than a waiting list control and reduced the potential for performance bias.

Treatment fidelity

Sessions will be audio recorded (if the young person provides consent). A sample of these sessions will then be assessed for adherence to the intervention manuals and competency by an independent rater. This will indicate whether these has been contamination between the two conditions due to the therapist being aware of both interventions.

Outcome measures

Primary

Feasibility data

- The number of eligible participants and willingness of schools and participants to take part
- Number of participants successfully completing intervention and reasons for drop-out
- Time needed to collect (through online methods) and analyse data
- Data completeness and reasons for missing data
- Unexpected adverse effects
- Follow-up rates, adherence/ compliance rates and response rates to questionnaires at each time point (recruitment, intervention and follow-up).

Acceptability data

Participants will be asked to complete a feedback questionnaire about their experiences of the intervention itself and of it being delivered in school.

Secondary

Clinical outcome measures will be collected at baseline (pre), post and 3-month follow-up. These include measures of depression and anhedonia to measure the proposed mechanisms of therapeutic change.

- Mood and Feelings Questionnaire (MFQ) (Angold et al., 1995) is a 33-item measure of low mood in young people rated on a 3-point Likert scale. We have removed the risk items so will administer a 29-item version.
- Snaith-Hamilton Pleasure Scale (SHAPS) (Snaith et al., 1995) is a measure of anhedonia, consisting of 14 items rated on a 4-point Likert scale.
- Positive and Negative Affect Schedule (PANAS) (Watson, Clark & Tellegen, 1988) is a self-report measure of affect and consists of 20-items rated on a 5-point Likert scale.
- The Prospective Imagery Task (PIT) (Holmes et al., 2008; Stober, 2000) adapted for use in young people by (Pile et al., 2018). Fourteen scenarios (7 positive and 7 negative) are presented to participants (e.g. "You will achieve something you wanted to"), who are asked to imagine each happening to them and then rate this mental image on a 5-point scale; 'No image at all' to 'Very clear and detailed'.
- Autobiographical Memory Task (AMT) (Williams & Broadbent, 1986) is a measure of memory specificity. Participants will be given an example of a specific memory and then asked to give a specific memory to ten cue words (five positive; five negative).
- Screen for Child Anxiety Related Disorders (SCARED, Birmaher et al., 1997) is a self-report measure of anxiety, consisting of 41 items rated on a 3-point Likert scale.
- Rosenberg Self Esteem Scale (RSES) (Rosenberg, 1965) is a 10-item self-report measure of self-worth, rated on a 4-point Likert scale.

Statistics and data analysis

All analyses will be conducted on an intent-to-treat basis:

- Descriptive statistics: including means and standard deviations for normally and not normally distributed data will be reported for key outcomes from the feasibility RCT data
- Recruitment and retention rates: will be described as percentages and predicted vs. actual recruitment rates will be recorded monthly
- Trial flow CONSORT diagram: will be used to show the number of approached participants, numbers eligible/ ineligible

Service user involvement

Service user advisory groups were consulted during the development of the intervention and their feedback was positive, identifying a unmet need for young people with depression and a treatment strategy that was novel to them.

Data management and dissemination

Participant data will be anonymised, and participants will be given a unique code. Consent forms will be stored separately. All anonymised data will be stored on a password-protected computer and backed up on an encrypted USB. We intend to disseminate the findings to the schools that participated in the research, as well as more widely through conferences and publications in peer-reviewed scientist journals. Following completion of the trial, the data set will be made publicly available.

Ethical issues and ethical approval

KCL ethics has granted ethical approval for the project (KCL Ethics Ref: HR-19/20-14899) to be delivered in school-settings. Ethical issues include ensuring informed consent is gained, disclosure of risk issues, confidentiality and potential to cause distress and stigma.

Informed consent: this will be sought at both the screening and intervention stages. The project will first be explained verbally to participants and they will be informed that participation is voluntary. At each stage participants will receive an information sheet which explains that they will be asked for informed consent before participation. Informed consent will be completed on Qualtrics, where participants will tick their agreement and provide their name and date of consent. This informed consent will be initially saved on Qualtrics. Should participants wish to have a copy of their consent form, it can be downloaded and saved as an encrypted file which can then be shared with the participant

Disclosure of risk issues: Prior to participating, the young person will be informed that everything they say is confidential unless the project researcher is concerned that they may be at risk to themselves or others. If participants make a disclosure, the project researcher will seek support from the clinical supervisor (VP) in supervision or during the session with the young person if immediate risk is indicated. The project researcher will then contact the pastoral lead/ gatekeeper at school, who will follow their school safeguarding procedures on managing the risk, including disclosure of risk to parents or local authorities (including social services and the police if illegal activities are indicated). All participants will be given a leaflet about mental health and where to access help. Depending on the nature of the disclosure, advice about help for young people will be given, including referral to local CAMHS services.

Potential to cause distress: it is possible that participants may experience distress during the therapy when describing feelings of low mood. Prior to the intervention, participants will be informed they can contact me in confidence to discuss any issues. Should any concerns need to be managed I will utilise my on-going supervision and if necessary, contact gatekeepers at participating schools.

Stigmatisation: this is an important issue and we have taken a variety of measures to ensure participants associated with the project will not be stigmatised. As screening and assessments will be online, young people will not see each other's responses. Young people who meet the eligibility criteria will be invited to the intervention stage via email or text message and if they wish to take part, they will need to contact me. This is to ensure their participation is voluntary and not identifiable to other students. Furthermore, whilst participants need to score above clinical cut-off to be eligible for the study, we state on our participant information sheet that "depending on responses to the questionnaires, we will ask pupils with a range of mood scores to take part in Stage 2". If participants do experience stigmatisation, we will liaise closely with the school and their policies on bullying to ensure the best course of action is taken. Participants may also discuss the issue of stigmatisation with me and are free to withdraw from the study at any time.

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