Study Protocol

Unique Protocol ID: EtikDnr2021-04357CUST1
Brief Title: Self-compassion Therapist-led Online Group Treatment for Adolescents With Distress, Anxiety, and Depression (CUST)
Official Title: The Effects of a Self-compassion Therapist-led Online Group Treatment for Adolescents With Distress, Anxiety and Depression
NCT number: 05448014
Document date: 1 July 2022

Study description

Brief Summary:

Background: Distress, anxiety and depression are highly prevalent in school health care or primary care. Many of these conditions remain undiscovered and/or untreated. Compassion-focused therapy (CFT) is effective in the treatment of adults' distress and depression, and the investigators will now evaluate the preliminary effect of a brief therapist-led online group CFT, feasibility, and acceptability in low-threshold distressed, anxious, and depressed adolescents. The investigators use online group CFT to increase availability.

Purpose: The purpose of this study is to determine whether therapist-led online group CFT is feasible and acceptable for the treatment of depression in adolescents between 15 and 20 years of age, in Sweden. The preliminary effect will be calculated to examine if a larger experimental randomized controlled trial is justified.

Study design: A two-arm (treatment group vs. control group) pilot randomized controlled trial will be carried out with 32 adolescents. The effect, feasibility, and acceptability of the therapist-led online CFT in groups will be evaluated.

Condition or disease: Distress, anxiety and depression

Intervention/treatment: Other: therapist-led online group compassion focused therapy; Other: Usual care treatment

Phase: Not applicable

Arms and Interventions

Experimental: therapist-led online CFT in groups

Seven sessions of therapist-led online compassion-focused therapy in groups of 4-8 adolescents with mild to moderate symptoms of distress, anxiety, or depression. Trained therapists administer the CFT program in face-to-face meetings.

Passive Comparator: Waitlist

Intervention/treatment

Other: Therapist-led online compassion-focused therapy in groups.

The intervention arm will receive seven sessions of therapist-led online CFT in groups. Internet-delivered CFT sessions 1,5h, will be delivered on a weekly basis and assisted by trained psychologists or psychotherapists in face-to-face meetings. The program is called "Compassion focused training for adolescents with stress". Topics covered in the program will include 1) what is compassion, 2) understanding myself, 3) life-compass, 4) self-compassion and my body, 5) feelings and compassion, 6) creating balanced thoughts, and 7) imagination.

Other: The waitlist control group will receive training after being on the waiting list but is not included in the main analyses. The result from this will be compared with the result of the RCT pilot study afterwards.

Primary outcome measure:

1.	The total score of Perceived Stress Scale, 14 items, 0 = never to 4 = very often Higher scores mean a worse outcome
2	The subscale Depression in Trauma Symptom Checklist for Children (TSCC), 9 item, 0 = never to 3 = almost always Higher scores mean a worse outcome
3.	The subscale Anxiety in Trauma Symptom Checklist for Children (TSCC) 9 item, 0 = never to 3 = almost always Higher scores mean a worse outcome

Feasibility: Drop-out rates and adherence

Acceptability: Self-report evaluations questions in a form and semi-structured focus interviews will be performed.

Secondary outcome measures:

1.	The Compassionate Engagement and Action Scale for Adolescents (CEASY). 27 items, 1 = never to 10 = always Higher scores mean a better outcome
2	The subscale PTSD in Trauma Symptom Checklist for Children (TSCC), 9 item, 0 = never to 3 = almost always Higher scores mean a worse outcome

3.	The subscale Dissociation in Trauma Symptom Checklist for Children (TSCC) 9 item, 0 = never to 3 = almost always Higher scores mean a worse outcome
4.	The subscale Anger in Trauma Symptom Checklist for Children (TSCC) 9 item, 0 = never to 3 = almost always Higher scores mean a worse outcome
5.	The Montgomery and Åsberg Depression Rating Scale for Youths (MADRS-Y) 12 item, 0 = never/normative in sentences to 6 = always/described pathology in sentences Higher scores mean a worse outcome
6.	The WHO-5 wellbeing index (WHO-5) 5 item, 0 = never to 5 = all the time Higher scores mean a better outcome
7.	The Difficulties in Emotion Regulation Scale (DERS) 16 item, 1 = almost never to 5 = almost always Higher scores mean a worse outcome
8.	The Situational Motivation Scale (SIMS) 16 item, 1 = corresponds not at all to 7 = corresponds exactly Higher scores mean a better outcome
9.	The Intrinsic and Extrinsic Motivation Scale (IEMS) 16 item, 1 = corresponds not at all to 5 = corresponds exactly Higher scores mean a better outcome

Eligibility Criteria

Ages Eligible for Study: 15 Years to 20 Years (Child, Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Symptoms of distress (≥ 22 in PSS) and/or
- Symptoms of anxiety (≥ 9 in subscale Anxiety in TSCC) and/or
- Symptoms of depression (≥ 10 in subscale Depression in TSCC)
- Adolescent giving informed consent
- Caregiver giving informed consent if needed
- Speaking Swedish
- Able to read and fill forms in Swedish without troubles
- At least one close and stable relationship with an adult
- Able to be in a group on the internet

Exclusion Criteria:

- Severe psychological problems that can be hindering for participation in a group treatment
- No close stable relationship with an adult
- Suicidal risk (4 or higher in item 12 in MADRS-Y, together with a clinical decision of active suicidal plans during the diagnostic screening interview)
- Anorexia Nervosa
- Autism
- Bipolar Disorder
- Current substance and alcohol dependence
- Current psychosis
- Current active psychotherapy
- Current deposit or withdrawal of antidepressant
- Prescribed medications for anxiety or depressive disorders do not exclude participants from the study, if the dosage had remained constant for at least one month.

Detailed Description:

Compassion focused therapy for depressed adolescents (CUST)

Introduction

Adolescence is a vulnerable period of growth and challenges, characterized by rapid physiological and emotional changes. All these changes happen at the same time as relationships expand. A developing self together with a pressure to "fit in" can lead to self-critic and distress. Without appropriate coping skills to manage these challenges, adolescents are more vulnerable to psychological problems. Distress, anxiety, and depression have also increased in the western world during the last years, and especially girls or young women are affected (WHO, 2019). In addition, depressive disorders are the single largest contributor to global disability (WHO, 2017). Adolescents-appropriate training in compassion may help adolescents successfully overcome the challenges in the future and help adolescents to take care of themselves.

Schools are not just about acquiring knowledge, they are playing a central role in cultivating necessary social, emotional, and ethical skills required to lead successful lives (Jazaieri, 2018). Recently, there has been a great interest in bringing mindfulness and compassion to educators and students.

The construct of compassion is defined by Paul Gilbert as a "sensitivity to suffering in self and others with a commitment to try to alleviate and prevent it" (Gilbert, 2014) and include compassion for oneself, compassion for others, and receiving compassion from others. Compassion strategies are core competencies in life, already taught by large religions as Christianity and Buddhism, but now in a modern version along with new neurobiological

research and cognitive behavior therapy interventions. These skills or strategies can be taught, but have not yet been widely used in the contexts of adolescents (Jazaieri, 2018).

Research supporting compassion focused therapy for depression

Compassion focused therapy (CFT) was developed two decades ago and is a well-established talking therapy for depression and stress (Gilbert, 2007). Compassion has a protective effect against depression and suicidality (Zeller et al., 2015), in youth. Training in compassion is linked to well-being and perceived life satisfaction (Kirby et al., 2017). Meta-analytic findings of CFT on adults has recently showed moderate effects on stress, depression and anxiety (Kirby et al., 2017). Studies with adolescents are few. For example one small study (Bluth et al., 2016) with 34 14-17 year old students found that a mindful self-compassion school program in six weeks was feasible and acceptable. The intervention group had significantly greater self-compassion and less depression than the waitlist control.

The CFT intervention

Compassion Focused Training (CFT). The investigators have developed a new manual for CFT training with seven modules (Dennhag, 2021) including 1) what is compassion, 2) understanding myself, 3) life-compass, 4) self-compassion and my body, 5) feelings and compassion, 6) create balanced thoughts, and 7) imagination. CFT is an internet-delivered (zoom or teams) real time group training (for 15-20 years old adolescents), 1,5h, in seven weeks. The youth will receive a manual for practice. The investigators were inspired by Professor Paul Gilbert, Mary Welford, and Elaine Beaumont's approach (Welford & Beaumont, 2020), but the investigators have shortened and adapted Welford and Beaumont manual to Swedish context. In addition, the investigators are influenced by cognitive behavior principles. Functional analyses and thoughts records are for example, used. The intervention focuses on the present and not on processing memories. The intervention is made for primary care and school health. A psychotherapist/psychologist or social worker will lead the training.

Theory behind the studies

Compassion focused therapy is a components-based approach that integrates evolutionary theory, neurobiology, attachment theory, affect theory, family theory, cognitive behavioral principles, and humanistic theory (Gilbert, 2014).

The originality of the project

Even though CFT has shown good results for adults, there are only a few small CFT studies on adolescents. None of them provide internet-delivered therapy. Our short internet-delivered group intervention for youths will be unique and could possibly be a good preventive and healing intervention for schools. Primary care and school health care need more efficient methods for both preventing and treating distress, anxiety, and depression.

Many barriers limit treatment uptake, such as limited number of trained therapists, costs, compliance issues such as time off work, and transportation, associated with the need to attend weekly appointments (Simon et al., 2021). Delivering CFT in groups on the internet may be an effective and acceptable alternative to therapist-delivered treatment in primary care and at school health care. especially for rural areas.

Internet delivered such as telehealth, minimize barriers in access to care and address health-care disparities. Furthermore, internet delivered therapy allows for culturally and linguistically competent providers to offer mental health services to adolescents who might not have access to such clinicians in their communities. Nevertheless, several challenges have been identified in the literature including technological issues (e.g., poor internet connection), privacy and confidentiality (e.g. finding a quiet and private location), and safety concerns (Simon et al., 2021; Stewart et al., 2017). More and better studies with more modern technology are needed to develop this further.

A quality assurance data plan has been written. The investigators will collect quantitative data through RED Cap, which is a web survey recommended by Umeå University (Umeå University, 2022a). Data from RED Cap is saved at Umeå University. Only anonymous data with code will be saved at RED Cap.

Multifactor authentication is required for logging in to "protective documents" at Umeå University, and also for RED Cap, Outlook, TEAMS and other O365 system. The investigators are storing sensitive data on Umeå University system for that: protective documents (Umeå University, 2022b).

The investigators are following Swedish archive laws and are using a Umeå University system for that (Umeå University & Clinical Science, 2022).

The investigators will do data checks to compare raw data over time if data quality is sustained. Check sum will be used for this.

A data dictionary that contains detailed descriptions of each variable used by the registry, including the source of the variable, and coding information if used and normal ranges if relevant, will be performed.

Standard Operating Procedures have been written to address registry operations and analysis activities, such as patient recruitment, data collection, data management, data analysis, reporting for adverse events, and change management.

Bluth, K., Gaylord, S. A., Campo, R. A., Mullarkey, M. C., & Hobbs, L. (2016). Making Friends With Yourself: A Mixed Methods Pilot Study of a Mindful Self-Compassion Program for Adolescents. *Mindfulness (N Y)*, *7*(2), 479-492. https://doi.org/10.1007/s12671-015-0476-6

Dennhag, I. (2021). *Att lära om Self-compassion [eng. To learn about Self-compassion]*. Clinical Science.

Gilbert, P. (2007). *Psychotherapy and counselling for depression* (3rd ed.). SAGE.

Gilbert, P. (2014). The origins and nature of compassion focused therapy. *British Journal of Clinical Psychology*, *53*(1), 6-41. https://doi.org/10.1111/bjc.12043

Jazaieri, H. (2018). Compassionate education from preschool to graduate school: Bringing a culture of compassion into the classroom. *Journal of Research in Innovative Teaching & Learning*, *11*(1), 22-66. https://doi.org/10.1108/JRIT-08-2017-0017

Kirby, J. N., Tellegen, C. L., & Steindl, S. R. (2017). A Meta-Analysis of Compassion-Based Interventions: Current State of Knowledge and Future Directions. *Behavior Therapy*, *48*(6), 778-792. https://doi.org/10.1016/j.beth.2017.06.003

Simon, N., Robertson, L., Lewis, C., Roberts, N. P., Bethell, A., Dawson, S., & Bisson, J. I. (2021). Internet-based cognitive and behavioural therapies for post-traumatic stress disorder (PTSD) in adults. *Cochrane database of systematic reviews*, *5*(5), CD011710-CD011710. https://doi.org/10.1002/14651858.CD011710.pub3

Stewart, R. W., Orengo-Aguayo, R. E., Cohen, J. A., Mannarino, A. P., & de Arellano, M. A. (2017). A Pilot Study of Trauma-Focused Cognitive-Behavioral Therapy Delivered via Telehealth Technology. *Child Maltreat*, *22*(4), 324-333. https://doi.org/10.1177/1077559517725403

Umeå University. (2022a). *REDCap - data collection in research studies (In Swedish: REDCap - Datainsamling vid forskningsstudier)*. https://www.aurora.umu.se/stod-och-service/it-och-digitala-tjanster/samla-in-data/datainsamling-forskning/

Umeå University. (2022b). *Storing of files with high level of security (In Swedish: Lagra filer med högt skyddsvärde i Skyddade dokument)*. Retrieved 2022-06-20 from https://www.aurora.umu.se/stod-och-service/it-och-digitala-tjanster/dokument-fillagring/skyddade-dokument/

Umeå University, & Clinical Science. (2022). *Research Archive Clinical Science (In Swedish Forskningsarkivet Klinisk Vetenskap)*. http://foark.klinvet.umu.se:5000/#/signin

Welford, M., & Beaumont, E. (2020). *The kindness workbook: Creative and compassionate ways to boost your wellbeing*. Robinson Publishing.

WHO. (2017). *Depression and other common mental disorders: Global health estimates* (Licence: CC BY-NC-SA 3.0 IGO, Issue. http://apps.who.int/iris/bitstream/handle/10665/254610/WHO-MSD-MER-2017.2-eng.pdf;jsessionid=5C6C365CE6CA46022D8AE57751200AE9?sequence=1

WHO. (2019). *Spotlight on adolescent health and well-being: Findings from the 2017/2018 health behaviour in school-aged children (HBSC) survey in Europe and Canada*. https://www.euro.who.int/en/publications/abstracts/spotlight-on-adolescent-health-and-well-being.-findings-from-the-20172018-health-behaviour-in-school-aged-children-hbsc-survey-in-europe-and-canada.-international-report.-volume-1.-key-findings

Zeller, M., Yuval, K., Nitzan-Assayag, Y., & Bernstein, A. (2015). Self-compassion in recovery following potentially traumatic stress: longitudinal study of at-risk youth. *Journal of Abnormal Child Psychology*, *43*(4), 645-653. https://doi.org/10.1007/s10802-014-9937-y