Counseling

Psychological interventions for cystic fibrosis patients

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Background

Cystic fibrosis has many psycho–social implications for patients and their relatives. These can stem from parental adaptation problems following diagnosis, negative illness perceptions, feeling 'different' and other associated developmental intrusions, mainly in adolescents. Psychological problems result in depression and anxiety that worsen the quality of life and the adherence to treatment.

Cognitive interventions, behavioural strategies (including behavioural contracting, bio-feedback, hypnosis and relaxation), creative/physical therapies (including music and movement therapy) and educational programs are effective for both treatment-related behavioural problems (e.g. poor feeding and airway clearance) and some psychological disorders (e.g. anxiety and depression).

However, outcome depends on patients' motivation to change and willingness to collaborate. Where this is absent, psychotherapies, less directive, but nonetheless effective, are utilised. Family therapy is also considered useful in addressing family dysfunction.

Issues

- To study efficacy of psychological interventions to provide improvement in psychological well-being in CF patients and their families, measured also as social functioning and adaptation to life with the disease
- To investigate if psychological intervention is associated with improvement of clinical outcomes, mainly nutrition and respiratory function
- To compare efficacy of different psychological interventions within major target areas (e.g. screening, diagnosis, transplantation) and towards different CF population targets on the basis of age and severity stage of the disease

What is known

One CDSR (Jones M, 2023) investigated interventions for improving adherence to airway clearance treatment and exercise in people with cystic fibrosis. Two RCTs (77 participants with CF; age range 2 to 20 years; 44 (57%) males) met the inclusion criteria of this review. One study employed an intervention to improve adherence to exercise and the second an intervention to improve adherence to ACT. Both studies measured outcomes at baseline and at three months, but neither study formally assessed the primary outcome of adherence and results were dependent on self?reported data. All evidence was graded as very low certainty. Authors are uncertain whether a music?based motivational intervention may increase adherence to ACTs or affect the risk of hospitalisation for a respiratory infection. They are also uncertain whether an educational intervention increases adherence to exercise or reduces the frequency of respiratory infection?related hospital admission. However, these results are largely based on self?reported data and the impact of strategies to improve adherence to ACT and exercise in children and adolescents with stable CF remains inconclusive. Given that adherence to ACT and exercise therapy are fundamental to the clinical management of people with CF, there is an urgent need for well?designed, large?scale clinical trials in this area, which should conform to the CONSORT statement for standards of reporting and use appropriate, validated outcome measures. Studies should also ensure full disclosure of data for all important clinical outcomes.

One CDSR (Dawson S, 2023) included 10 trials (1642 participants) in the review (children and adolescents in four trials; adults in five trials; and children and adults in one trial). Nine trials compared a psychological intervention with usual care. One trial compared a psychological intervention with an active comparator (education plus problem?solving (EPS)). Five ongoing trials were identified. Due to the limited quantity of trials included in this review, as well as the clinical and methodological heterogeneity, it was not possible to identify an overall intervention effect using meta?analysis. Some moderate?certainty evidence suggests that psychological interventions (compared with usual care) probably improve adherence to inhaled therapies in people with CF, without increasing treatment?related adverse events, anxiety and depression (low?certainty evidence). In future review updates (with ongoing trial results included), the authors hope to be able to establish the most effective BCTs (or 'active ingredients') of interventions for improving adherence to inhaled therapies in people with CF. Wherever possible, investigators should make use of the most objective measures of adherence available (e.g. data?logging nebulisers) to accurately determine intervention effects. Outcome reporting needs to be improved to enable combining or separation of measures as appropriate. Likewise, trial reporting needs to include details of intervention content (e.g. BCTs used); duration; intensity; and fidelity. Large trials with a longer follow?up period (e.g. 12 months) are needed in children with CF. Additionally, more research is needed to determine how to support adherence in 'under?served' CF populations.

One CDSR protocol (Jones M, 2020) plans to include randomised controlled trials (RCTs) and quasiRCTs. Participants will be adults and children (from aged eight years upwards) with CF. Interventions will include any intervention aimed at enhancing adherence to physiotherapy versus no intervention, usual care or another intervention aimed at enhancing adherence to physiotherapy.

A CDSR (Irons JY, 2019) included only 1 small RCT (n = 40) undertaken at two paediatric hospitals in Australia. The study evaluated the effects of a singing program on the quality of life and respiratory muscle strength of hospitalised children with cystic fibrosis (mean age 11.6 years, 35% males). This study was limited by a small sample size and a high drop-out rate (21%). There were no significant differences between the groups at either post-intervention or follow up; although by the end of treatment there were some within-group

statistically significant increases for both singing and control groups in some of the domains of the quality of life questionnaire Cystic Fibrosis Questionnaire-Revised (e.g. emotional, social and vitality domains). For the respiratory muscle strength indices, maximal expiratory pressure at follow up (six to eight weeks post-intervention) was higher in the singing group, mean difference 25.80 (95% confidence interval 5.94 to 45.66). There was no significant difference between groups for any of the other respiratory function parameters (maximal inspiratory pressure, spirometry) at either post-intervention or follow up. This CDSR conlcuded that there is insufficient evidence to determine the effects of singing on quality of life or on the respiratory parameters in people with cystic fibrosis. However, there is growing interest in non-medical treatments for cystic fibrosis and researchers may wish to investigate the impact of this inexpensive therapy on respiratory function and psychosocial well-being further in the future.

One CDSR (Malone H, 2019) evaluated the interventions for promoting shared decision-making in CF children or adolescents aimed at children or adolescents, their parents or healthcare professionals, or any combinations of these groups, compared with usual care or to alternative SDM promotion strategies for the same group of people. No eligible RCTs were identified for inclusion in this systematic review. this review identified a gap in research; the authors hope that this result improves the awareness amongst researchers of the need to design high?quality shared decision?making interventions for young people with CF, perhaps adapted from existing models for adults, and to test these interventions and children's preferences in RCTs. It is also important to target health professionals with evidence?based education programmes on shared decision?making and a need for international consensus on addressing the variability in education programmes.

One CDSR and updated in 2016 (Irons JY, 2016) on singing therapy, only 1 study included, concluded that this non-medical treatment needs further investigation.

One CDSR (Goldbeck L, 2014) including 16 studies for a total of 556 CF people, is available. This review showed that there is some evidence that behavioural interventions targeting nutrition and growth in children (4 to 12 years) with cystic fibrosis are effective in the short term. Evidence was found that providing a structured decision-making tool for patients considering lung transplantation improves patients' knowledge of and expectations about the transplant, and reduces decisional conflict in the short term. One study about training in biofeedback-assisted breathing demonstrated some evidence that it improved some lung function measurements.

One CDSR (Savage E, 2014), evaluated the effects of self-management education interventions on improving health outcomes (pulmonary function, weight, dietary fat intake, etc) for patients with cystic fibrosis and their caregivers. Results suggest that behavioural interventions are able to improve psychological well-being and that the psycho–educational ones are able to improve self-management of the treatment protocol.

One RCT (Montero-Ruiz A, 2020) investigated the effects of music therapy as an adjunct to chest physiotherapy in children (age: 2-17 years) with cystic fibrosis. The authors compared the use of specifically composed music (Treated Group, TG), music that the patient liked (Placebo Group, PG), and no music (Control Group, CG) during the usual ACT routine. Enjoyment increased after the use of the specifically composed music (children +0.9 units/parents +1.7 units; p<0.05) compared to enjoyment with no music (0 units) and familiar music (+0.5 units). Perception of time was 11.1 min (±3.9) less than the actual time in the TG (p<0.05), 3.9 min (±4.2) more than the actual time in the PG and unchanged in the CG. The potential cost saving related to respiratory exacerbations was €6,704.87, while the cost increased to €33,524.35 in the CG and to €13,409.74 in the PG. The authors concluded that specifically composed, played and compiled instrumental recorded music is an effective adjunct to ACT to establish a positive response and is an efficient option in terms of avoided costs.

One RCT (Wood J, 2019) investigated a smartphone application for reporting symptoms in adults with cystic fibrosis. 60 CF patients (29 female, aged [mean+/-SD] 31+/-9years, FEV1 60+/-18% predicted) were randomised to intervention (use of the app weekly or sooner if symptoms had worsened) or control (usual care). The primary outcome measure was the number of courses and days of intravenous (IV) antibiotics. In conclusion this study showd that the use of an app reduced time to detect respiratory exacerbations that required antibiotics, however did not demonstrate a clear effect on the number of courses of IV antibiotics.

One single centre, non randomized and non controlled prospective study (Skov M, 2018) 1 year long in Denmark was focused on a transitional programme started at the age of 12 years. A well structured transition programme for CF patients as young as 12 years of age proved to be both feasible and sustainable.

One recent RCT (Moola FJ, 2017) evaluated the effects of physical activity counseling in 13 children between 8 and 18 with Cystic Fibrosis. The intervention was found to be feasible and acceptable with good recruitment, retention, adherence, and acceptability.

One RCT (Belsky J, 1994) studied self-hypnosis efficacy in 12 CF patients aged 7 to 18 years: significant improvement in psychological well-being and in lung function tests were demonstrated in the intervention group.

In conclusion:

Psychological intervention, in addition to standard multidisciplinary care, has a role in the treatment protocol of CF patients. This is demonstrated above all in the field of caloric intake to improve nutritional status.

Self-management education interventions (training programme for managing cystic fibrosis in general, education specific to aerosol and airway clearance treatments, general and disease-specific nutrition education) in children and adults with cystic fibrosis resulted in poor improvement of patient’s knowledge and in positively changing of a small number of behaviours in both patients and their caregivers.

A multicenter RCT (Quittner AL, 2019) including 607 adolescents with CF (11-20 years) compared a brief problem-solving + education intervention (IMPACT) vs standard care. Results showed that the IMPACT intervention did not improve medication adherence or health outcomes over 12months. Challenges to implementing the intervention as intended during busy clinic visits were identified.

A randomized feasibility trial (Hind D, 2019) in 2 CF centers investigated supporting medication adherence for adults (16 years and holder) with cystic fibrosis. The intervention consisted in linking nebuliser use with data recording and transfer capability to a software platform, and behavioural strategies to support self-management delivered by trained interventionists (n = 32); the control group (n= 32) received face-to-face meetings every 3 months with CF team. Interventionists delivered insufficient numbers of review sessions due to concentration on participant recruitment. This left interventionists insufficient time for key intervention procedures. With improved research processes and lower monthly participant recruitment targets, a full-scale trial is feasible.

A qualitative interview study undertaken concurrently with a pilot randomized controlled trial (Drabble S, 2020) investigated the mechanisms associated with effective telehealth interventions for self-management operated within a new intervention. The intervention was modified to strengthen mechanisms of action based on these findings, for example delivery through an app accessed via mobile phones, and then tested in a randomized controlled trial in 19 UK cystic fibrosis centers. 25 semi-structured interviews were conducted with three interventionists at two time points.

A prospective quality improvement study (Reamer C, 2020) ivestigated the effectiveness of a modified Re-Education of Airway Clearance Techniques (REACT) programme in CF children aged >6 years. Outcome measures were assessed for our entire programme via the CF Foundation Patient Registry (CFFPR) and statistical process control. Comparisons were also made before and after REACT for outcome measures. By the end of implementation, monthly participation rate achieved 100%. Using CFFPR data and SPC, median ppFEV(1) increased by 3.9%, whereas only body mass index (BMI) as a secondary outcome increased. Comparison of pre and post REACT showed improvements in average ppFEV(1) (95% vs 96%, p<0.0001), FEF(25%-75%) (82% vs 83%, p=0.0590), rate of ppFEV1 decline (+2% vs -4%, p=0.0262) and BMI percentile (57% vs 60%, p<0.0001). Implementation of a modified REACT at Lurie Children's paediatric CF programme led to an increase in ppFEV(1), FEF(25%-75%) and BMI percentile.

A clinical european study (Calvo-Lerma J, 2021) conducted in 84 CF children with PI followed in 6 CF centres investigated the use of a self-management mobile app to self-monitor dietary intake. Three-days food records were collected at baseline and after 3 and 6 months. Compared to baseline, better macronutrient distribution was registered increasing protein and lipid by 1.0 and 2.1% of the total energy intake, respectively, by the end of the study and decreasing carbohydrate intake. This app could become a useful tool to achieve adherence to guideline recommendations, if validated during a longer period of time or against a control group.

One pilot RCT (Bathgate CJ, 2022) investigated if telehealth intervention was able to reduce symptoms of depression and anxiety in adults with cystic fibrosis. Patients were randomly assigned to either six telehealth sessions (CALM; n = 15) or treatment-as-usual (TAU; n = 16). Based on these preliminary results CALM promise as an intervention to reduce symptoms of depression and anxiety and improve coping and HrQOL. A multi-site RCT is needed to confirm thede data.

One interventional, non randomized study (Friedman D, 2022) involved 14 CF adults with mild depression and/or anxiety symptoms. Intervention consisted in a cystic fibrosis (CF)-specific cognitive-behavioral therapy (CF-CBT). The 8-session CF-CBT was delivered in-person and via audio telehealth. A total of 108 sessions were conducted; 13 adults completed the intervention; 1 discontinued early. Engagement, homework completion, and treatment acceptability were highly rated (mean?=?30; SD?=?2, range: 27-32 on a 32-point scale). Fidelity scores ranged from 85.7% to 93.6%. Large ES changes reflected improvements in depressive symptoms (-0.83), CFQ-R (Vitality scale: 1.11), and Relaxation Skills (0.93); moderate ES for CFQ-R Role Functioning (0.63), Awareness of Tension (0.62), Coping Confidence (0.70) and CF-specific Coping (0.55); and small ES for anxiety symptoms (-0.22), perceived stress (-0.25), Behavioral Activation (0.29), and several CFQ-R domains, including Emotional Functioning (0.29). Two CFQ-R subscales decreased (Body Image, Eating Concerns). Results indicated feasibility and acceptability of CF-CBT and its integration into team-based CF care with promising effectiveness, especially for depression. A multicenter randomized controlled trial of CF-CBT will further examine effectiveness of a CF-specific integrated care model.

One RCT (Bradley JM, 2024) explored the effectiveness of supporting adherence to nebuliser medication in adults with cystic fibrosis. 19 CF centres, with 32 interventionists, 305 participants in the intervention group, and 303 participants in the standard care arm. Fidelity of the CFHealthHub intervention (a multi-component self-management intervention developed to reduce pulmonary exacerbations in adults with Cystic Fibrosis (CF) by supporting adherence to nebuliser medication. Interventionists underwent training and competency assessments to be deemed certified to deliver the intervention) and standard care was assessed using different methods for each of the five fidelity domains defined by the Borrelli framework: study design, training, treatment delivery, receipt, and enactment. Study design ensured that the groups received the intended intervention or standard care. Interventionists underwent training and competency assessments to be deemed certified to deliver the intervention. Audio-recorded intervention sessions were assessed for fidelity drift. Receipt was assessed by identifying whether participants set Action and Coping Plans, while enactment was assessed using click analytics on the CFHealthHub digital platform. Design: There was reasonable agreement (74%, 226/305) between the expected versus actual intervention dose received by participants in the CFHealthHub intervention group. The standard care group did not include focused adherence support for most centres and participants. Training: All interventionists were trained. Treatment delivery: The trial demonstrated good fidelity (overall fidelity by centre ranged from 79 to 97%), with only one centre falling below the mean threshold (>?80%) on fidelity drift assessments. Receipt: Among participants who completed the 12-month intervention, 77% (205/265) completed at least one action plan, and 60% (160/265) completed at least one coping plan. Enactment: 88% (268/305) of participants used web/app click analytics outside the intervention sessions. The mean (SD) number of web/app click analytics per participant was 31.2 (58.9). Additionally, 64% (195/305) of participants agreed to receive notifications via the mobile application, with an average of 53.6 (14.9) notifications per participant. The study demonstrates high fidelity throughout the RCT, and the CFHealthHub intervention was delivered as intended. This provides confidence that the results of the RCT are a valid reflection of the effectiveness of the CFHealthHub intervention compared to standard care.

A Randomized-controlled trial (Donmez H, 2024) evaluated the effectiveness of a parent empowerment intervention for caregivers of children with cystic fibrosis. 48 parents (caregivers) of children with CF were enrolled. A parent empowerment intervention based on nursing education (PEINE). Participants were randomly assigned to an intervention (n = 24) and a control group (n = 24). The intervention group received PEINE and standard care and treatment for ten weeks. The control group received standard care and treatment. Data were collected using a Disease Information Survey (DIS), the Ways of Coping Inventory (WCI), the Problem-Solving Inventory (PSI), and the Cystic Fibrosis Questionnaire (CFQ-R). Nursing interventions were effective (p < .001). There was no significant difference in the mean pre-test-post-test PSI scores (d: 0.378 [CI: -0.221-0.972], post-test WCI scores (d: 0.239 [CI:-0.356-0.831]) between the intervention and control groups (p>.05). There was a significant difference in the mean post-test CFQ-R scores between the intervention and control groups (d: 1.363 [CI: l.698, 2.015]);(p < .001). PEINE increased the intervention group participants develop disease-management skills. However, the increase in their PSI and WCI scores was statistically insignificant. PEINE also increased the quality of life of children with CF.

A multisite telehealth randomized controlled trial (Bathgate CJ, 2024) investigated through "Coping and Learning to Manage Stress with CF" (CALM) how to reduce depression and anxiety symptoms in adults with cystic fibrosis reporting mild to severe symptoms of depression and/or anxiety. Patients were randomized to receive CALM immediately (immediate, n = 66) or after a 13-week delay

(waitlist, n = 66). Compared to the waitlist group, those that received CALM immediately reported lower depression and anxiety symptoms post-intervention and at 1-month follow-up (ps<0.001). For depression there was a large effect size post-intervention (d = 0.85) and a medium effect size at 1-month follow-up (d = 0.70); anxiety had a medium effect size post-intervention (d = 0.65) and at 1-month follow-up (d = 0.66). The immediate group also reported significantly higher coping self-efficacy, less stress, and increased vitality post-CALM and at 1-month follow-up (ps<0.01). Treatment gains were maintained at 3-month follow-up for all outcomes. CALM was efficacious for adults with CF in reducing symptoms of depression, anxiety, and perceived stress while improving coping self-efficacy and vitality with evidence of treatment sustainability. Next steps are dissemination and implementation to CF psychosocial clinicians.

A 3-year, multi-site, telehealth-delivered randomized trial (O'Hayer CV, 2024) sought to determine whether Acceptance and Commitment Therapy (ACT with CF) is superior to supportive psychotherapy (SP), in improving psychological functioning for adults with CF. 124 adults with CF (mean age 25 years [SD = 12]), female (75 %), on CFTR modulators (67 %), psychotropic medication(s) (60 %), with previous psychotherapy engagement (72 %) and elevated anxiety and/or depressive symptoms were recruited coincident with the first COVID lockdown, from Thomas Jefferson University Hospitals, University of Virginia, Augusta University, Duke University Medical Center, and social media. Participants were randomized to 6 weeks of either ACT with CF or SP, delivered via Zoom. They completed measures of psychological functioning: depression (BDI-II), anxiety (BAI), cognitive fusion (CFQ-13), acceptance and committed action (AAQ-II); and barriers to adherence at baseline, post-treatment, and at 3-months follow-up. Biobehavioral outcomes, including CF severity and treatment burden, were gathered using EMR data. Treatment effects were evaluated using analysis of covariance, controlling for baseline levels of respective outcomes, age, biological sex, and FEV_1. ACT demonstrated greater improvements in psychological functioning at 6-weeks (mean score = 57.3 [51.6, 63.0]) relative to SP (mean score = 67.8 [62.2, 73.5], Cohen's d = 0.59, *P* = .017), with largest improvements in cognitive fusion (CFQ-13) and acceptance and committed action (AAQ-II). Treatment improvements in psychological functioning persisted at 3-months (ACT: 59.7 (53.5, 65.9) vs. SP: 69.0 [62.6, 75.4], Cohen's d = 0.40, *P* = .041), with ACT demonstrating continued improvements in the CFQ-13 and AAQ-II. Negative affect scores were not consistently improved on our mean-rank composite outcome variable (Cohen's d = 0.22, *P* = .170), despite post hoc reductions in BDI-II scores (ACT: ?7.4 [?9.4, ?5.4] vs. SP: ?4.5 [?6.4, ?2.6], *P* = .040). Improvements in psychological flexibility (CFQ-13 and AAQ-II) were also robustly associated with reductions in negative affect (B = ?0.45, *P* < .001). Individuals in ACT with greater baseline barriers to medication adherence reported greater reductions in barriers after treatment (*P* = .026). Individuals with lower baseline FEV_1/FVC ratios (e.g. ? 65 %) demonstrating greater improvements in ACT compared with SP (ACT: 7.3 [1.7, 12.8] vs. SP: 1.3 [?3.2, 5.8], *P* = .036 for interaction). In conclusion ACT with CF was superior to SP in improving psychological functioning among adults with CF and elevated psychological distress, with additional benefits in secondary biobehavioral outcomes in a subset of individuals with greater medical burden. Improvements in psychological flexibility strongly associated with reductions in negative affect.

An RCT (Kilic K, 2025) investigated the effects of telerehabilitation vs home-based exercise on muscle function, physical activity, and sleep in 30 children with CF (mean age = 10.2?±?1.9 years). The 1-min STS significantly improved in the TG compared with the HG (p???.001, ?(p)(2)?=?0.474). The sit-up (p?=?.005, ?(p)(2)?=?0.247), pushup (p?=?.002, ?(p)(2)?=?0.180), squat (p?=?.002, ?(p)(2)?=?0.284), and plank (p?<?.001, ?(p)(2)?=?0.360) test scores were significantly improved in the TG compared to the HG. No significant changes between groups were seen for PA (p?=?.261, ?(p)(2)?=?0.045), ESS (p?=?.160, ?(p)(2)?=?0.069), or PSQ (p?=?.763, ?(p)(2)?=?0.003). In conclusion, children who received TG improved muscle function more than children who received an HG. The effectiveness of longer term TG programs should be investigated in children with CF.

An RCT (Balc? MS, 2025) compared the effect of the modified CF S.O.B.E. program versus the standard CF S.O.B.E. program on the knowledge improvement of pwCF. To address the gap in transition readiness, The Marmara University (MU) Selim Coremen CF Center, the largest in Turkey adopted the CF S.O.B.E. program, which is derived from the Turkish initials for responsibility, self-care, independence, and education. 81 pwCF aged 16-25, divided into two groups: the standard CF S.O.B.E. group (n?=?39) and the modified group (n?=?42). The standard group received face-to-face education. Both groups participated in online training sessions and received written materials. The standard group showed higher post-training scores in "Lung Health and Airway Clearance" and "Equipment Maintenance and Infection Control" (p?=?0.014 and 0.002). Modified group showed improvements in all KAQs except "Lung Health and Airway Clearance", "CF-related Liver Disease," "Pancreatic Insufficiency and Nutrition," and "Male Sexual Health." Regarding Pancreatic Insufficiency & Nutrition and CF-related Diabetes, individuals with these conditions demonstrated higher pretest scores than those without these conditions (p?=?0.01 and 0.002, respectively). Both groups and their parents reported high satisfaction, and healthcare providers endorsed the program's effectiveness. This study demonstrated the CF S.O.B.E program's success in enhancing knowledge, disease management skills, and self-confidence among pwCF. While the modified CF S.O.B.E program may be suitable for resource-limited centers, the priority should be to implement the standard program due to its superior outcomes in self-confidence and disease management. This study lays the foundation for incorporating CF S.O.B.E as a standard practice and evaluating its long-term clinical impact.

An RCT (Maritescu A, 2025) investigated the effects of progressive muscle relaxation on mental health and sleep quality in 22 adults with Cystic Fibrosis. Progressive muscle relaxation (PMR); standard pulmonary rehabilitation (PR). Patients were randomly assigned to either the intervention group (PR + PMR) or the control group (PR only). Assessments were performed at baseline, after 21 days of intervention, and at the 48-day follow-up. Outcome measures included the CFQ-R for quality of life, the HADS for mental health, and the PSQI for sleep. Compared to the control group, participants who practiced PMR experienced significant reductions in anxiety (p = 0.05) and depression (p = 0.02) at the final assessment. A significant improvement in sleep quality was also observed (p < 0.01). No relevant differences were found in pulmonary function or performance on the six-minute walk test. In conclusion, integrating PMR into pulmonary rehabilitation programs may be an effective strategy for improving mental health and sleep in patients with CF. Due to its accessibility and ease of implementation, PMR could be adopted as a complementary method in the holistic care of these patients.

An RCT (Omidi A, 2025) evaluated the impact of Mandala coloring on anxiety of 120 children with CF aged 6-18 years with CF with mild-to-moderate anxiety. An analysis of the mean anxiety scores before and after the intervention showed a significant decrease in the anxiety level in the Mandala group (Z = -3.74, p < 0.05). Moreover, a significant decrease was observed after the intervention between the children in the mandala and control groups in terms of average anxiety levels (U = 1206, p < 0.05). An intergroup comparison showed that state anxiety was significantly different between the two groups (U = 1143, p < 0.05), but no statistical difference was observed in terms of trait anxiety (p > 0.05). The results indicated that holding six mandala coloring sessions reduced the anxiety of children with CF. Thus, mandala coloring is recommended as a complementary non-pharmacological method to reduce children's

anxiety.

Unresolved questions

If and which kind of psychological intervention is associated with clinical outcomes improvement.

Timing and modality to address CF people to psychological interventions.

Several clinical trials are ongoing, dealing:

- with self-management interventions
- with a behavioural and nutritional intervention
- with singing
- with an intervention to improve adherence
- with a support programme for adolescents

An ongoing RCT (NCT03637504) evaluating the feasibility of a mobile medication plan application in CF patient care (patients' age: 12 and older) was completed.

An ongoign RCT (NCT03921229) will evaluate the tele-coaching intervention in CF patients (14 years of age and older) to improve treatment adherence in CF.

One ongoing trial (IRCT20180501039489N2) will investigate the effect of family empowerment on the coping strategies of parents of children with cystic fibrosis.

One ongoing RCT (NCT03992027) will evaluate how a cognitive-behavioral skills-based program to promote emotional well-being for adults wtih Cystic Fibrosis is able to pèrevent depression and ansiety.

One trial (ACTRN12619000009112) will explore anxiety disorders in children with cystic fibrosis and their families and provide a proof-of-concept trial of the Fear-less Triple P intervention. The Fear-Less Triple P workshop intervention is a one-day (6 hour) parent group workshop with a follow-up implementation phone call one week later. The workshop covers the following topics: Education about anxiety and its development;
Strategies for promoting emotional resilience in children (‘emotion coaching’); Cognitive behavioural strategies for managing anxiety; Strategies for managing children’s anxiety.

Keywords

Biofeedback- hypnosis- and relaxation; Psychoeducation;