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| Class | Attributes | Manual extraction | LLM extraction | TP, FP, FN |
| Study | Study Name | Extending research on Emotion Regulation  Individual Therapy for Adolescents (ERITA)  with nonsuicidal self-injury disorder: open  pilot trial and mediation analysis of a novel  online version | Extending research on Emotion Regulation Individual Therapy for Adolescents (ERITA) with nonsuicidal self-injury disorder | TP |
| Authors | Johan Bjureberg1\* , Hanna Sahlin1 , Erik Hedman-Lagerlöf2 , Kim L. Gratz3 , Matthew T. Tull3 , Jussi Jokinen1,4, Clara Hellner1 and Brjánn Ljótsson | Johan Bjureberg, Hanna Sahlin, Erik Hedman-Lagerlöf, Kim L. Gratz, Matthew T. Tull, Jussi Jokinen, Clara Hellner, Brjánn Ljótsson | TP |
| Publisher | BMC Psychiatry | BMC Psychiatry | TP |
| PublishDate | 11.10.2018 | 2018-10-10 | FP |
| Design | uncontrolled open trial | Uncontrolled open pilot trial | TP |
| Objective | The present study examined the feasibility, acceptability, and utility of an online version of ERITA. | To examine the feasibility, acceptability, and utility of an online version of Emotion Regulation Individual Therapy for Adolescents (ERITA). | TP |
| Hypothese | Online treatments carry the potential to increase the availability of evidence-based treatments. Emotion regulation individual therapy for adolescents (ERITA) has shown promise in the treatment of adolescents with NSSID. | Online ERITA will be feasible, acceptable, and result in improvements in NSSI and related outcomes, mediated by improved emotion regulation. | TP |
| Interventions | Content | The adolescent treatment included 11 online modules adapted from the ERITA manual. 6 parents modules every other week.  Post-treatment and follow-up assessments were administered directly after treatment completion (i.e., 11 weeks after treatment start) and at 3 and 6 months post-treatment completion.  The treatment platform was completely web-based | 11 adolescent and 6 parent online modules adapted from ERITA, including emotion awareness, impulse control, emotional acceptance, validation, and relapse prevention. Delivered through web platform and mobile app. | TP |
| Exposure quantity | 11 | 11 | TP |
| Duration | 12 weeks | 12 weeks | TP |
| Activities to Increase Compliance or Adherence | The psychologist reviewed the participants’ responses and provided written feedback through the platform. In the case of participant inactivity, the psychologist reminded the participant through text messages or telephone calls. Further, the psychologist helped problem solve, guide participants through the program, and assist with the homework assignments when necessary. | Therapist contact through feedback, reminders by text or phone, mobile app for homework and monitoring. | TP |
| Intervention Delivery | Unit of Delivery | Individual adolescent and parent modules | Individual adolescent and parent modules | TP |
| Setting | Web based platform | Online via secure web platform and mobile app | TP |
| Time Span | 12 weeks | 12 weeks | TP |
| Intervention Deliverer | clinical psychologist | Licensed clinical psychologists | TP |
| Analysis | Unit of Analysis | Individual adolescent, parent | Individual adolescent | TP |
| Recruitment | Setting | Online, mental health services (CAMHS) | Child and adolescent mental health services, community via newspaper and social media | TP |
| Location | Stockholm, Sweden | Stockholm, Sweden | TP |
| Outcomes | Primary Outcome | NSSI frequency reduction (DSHI-9) | NSSI frequency reduction (DSHI-9) | TP |
| Secondary Outcome | 36-item Difficulties in Emotion Regulation Scale (DERS), 11-item behavior supplement to the Borderline Symptom List (BSL), Borderline Personality Feature Scale for Children (BPFS-C), 7-item Acceptance and Action Questionnaire (AAQ-II),  Children’s Global Assessment Scale (CGAS),  Children’s Negative Emotions Scale – Adolescent version (CCNES-A) | Emotion dysregulation (DERS), global functioning (CGAS), BPD features (BPFS-C), psychological flexibility (AAQ-II) | TP |
| Validated Instruments | DSHI-9, DERS, CGAS, BPFS-C, AAQ-II, BSL, CCNES-A | DSHI-9, DERS, CGAS, BPFS-C, AAQ-II – validated psychometric tools for adolescents | TP |
| Binding | Accomplishment | - | Not applicable due to open design. | TN |
| Assignment | - | No blinding; open pilot trial design. | TN |
| Participation criteria | Min Age | 13 | 13 | TP |
| Max Age | 17 | 17 | TP |
| Eligibility Criteria | inclusion criteria for the adolescents were: (a) 13–17 years of age; (b) meeting diagnostic criteria for NSSID [2]; (c) having engaged in ≥1 NSSI episode during the past month; (d) having at least one parent who committed to participate in the parent program; and (e) stability of psychotropic medications (if any) for at least 2 months. Exclusion criteria for the adolescents were: (f ) severe suicidal ideation; (g) a diagnosis of psychotic or bipolar I disorder or ongoing (past month) substance dependence; (h) ongoing dialectical behavioral therapy or mentalization-based treatment; and (i) insufficient understanding of the Swedish language. | Aged 13–17, met diagnostic criteria for NSSID, ≥1 NSSI in past month, at least one participating parent, stable medication ≥2 months; excluded for severe suicidal ideation, psychosis, bipolar I, recent substance dependence, concurrent DBT/MBT, or insufficient Swedish. | TP |
| Sample | Sample Size | 25 | 25 | TP |
| Determination | - | 25 of 60 screened families met eligibility; no formal power analysis reported. | TN |
| Explanation Inherim Analyses and Stopping Rule | - |  |  |
| Statistical Methods | Primary Outcome Analysis | Generalized estimation equations (GEE) with exchangeable working correlation structure along with robust error estimations were used to model change in outcome measures across the treatment and follow up periods | Generalized Estimating Equations (GEE) were used to model change in NSSI frequency (DSHI-9) across pre-treatment, post-treatment, 3-, and 6-month follow-up. | TP |
| Additional Analysis | change in emotion regulation difficulties as a mediator of improvements in NSSI and self-destructive behaviors during treatment in two sets of mediation analyses – regression analysis | Subgroup and mediation analyses explored whether improvements in emotion regulation mediated changes in NSSI and self-destructive behaviors. | TP |
| Missing Data Handling | included regression weights in the GEE models that were inversely related to the probability of a value being observed as a function of time | Regression weights inversely related to the probability of value observation were used under the assumption of data missing at random. | TP |
| Statistical Software | R version 3.3.1 | Statistical analyses were conducted using R version 3.3.1. | TP |
| Assignment Methods | Method to Assign Units to Study Conditions | - | No assignment to different conditions; this was an uncontrolled open trial. | TN |
| Unit of Assignment | Individual adolescent, parent | Individual adolescent | TP |
| Restrictions | - | Not applicable due to lack of condition assignment. | TN |
| Bias Minimization Method | - | No randomization; selection bias potentially mitigated by inclusion criteria and reporting per TREND guidelines. | TN |
| Other Methods | Methods to Account Variance | - | Not applicable; unit of analysis matches unit of assignment (individual adolescent). | TN |
| Recruitment Methods | Participants were self-referred via newspaper ads, social media, and national website or referred from CAMHS | Participants were self-referred or referred from CAMHS via emails, internal website, newspaper ads, social media, and national website. | TP |
| Sampling Methods | eligibility screening | No systematic sampling plan; convenience sample based on eligibility screening. | TP |
| Quality Enhancing Methods | - | Validated instruments (e.g., DSHI-9, DERS) used; high internal consistency for all outcome measures. | TP |
| Data Collecting Methods | Weekly modules responses | Weekly and periodic online self-report measures and clinician-rated interviews; some assessments conducted via phone or in person. | TP |
| Intervention Delivery Methods | Delivered entirely online via web platform and mobile app; weekly modules with asynchronous psychologist feedback. | Delivered entirely online via secure web platform and mobile app; weekly modules with asynchronous psychologist feedback. | TP |

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| Class | Attributes | Manual extraction | LLM extraction | TP, FP, FN |
| Study | Study Name | Effects of a job crafting intervention  program on work engagement among  Japanese employees: a pretest-posttest  study | Effects of a job crafting intervention program on work engagement among Japanese employees | TP |
| Authors | Asuka Sakuraya1\*, Akihito Shimazu1 , Kotaro Imamura1 , Katsuyuki Namba2 and Norito Kawakami1 | Asuka Sakuraya, Akihito Shimazu, Kotaro Imamura, Katsuyuki Namba, Norito Kawakami | TP |
| Publisher | BMC Psychology | BMC Psychology | TP |
| PublishDate | 24.10.2016 | 2016-10-17 | FP |
| Design | pre- and post-intervention study was conducted. There was no control group | Pretest-posttest study without control group | TP |
| Objective | effectiveness of a newly developed job crafting intervention program on work engagement (as primary outcome), as well as job crafting and psychological distress (as secondary outcomes) | To investigate the effectiveness of a newly developed job crafting intervention program on work engagement among Japanese employees | TP |
| Hypothese | job crafting intervention program may be effective to increase work engagement. We expect that the scores of job crafting (for manipulation check) and work engagement (primary outcome) will increase at Time 2 (post-intervention) and at Time 3 (one-month followup) than compared to Time 1 (baseline). In addition, the score of psychological distress (secondary outcome) will decrease at Time 2 and Time 3 compared to Time 1. | The intervention will increase work engagement and job crafting, and decrease psychological distress | TP |
| Interventions | Content | job crafting intervention program consisted of two 120-min sessions with a two-week interval between them, based on the job crafting theory of Wrzesniewski and Dutton | Two 120-minute job crafting training sessions over two weeks based on Wrzesniewski and Dutton model; involved case study, group sharing, planning, and reflection | TP |
| Exposure quantity | 2 | 2 | TP |
| Duration | 120 minutes per session | 120 minutes per session | TP |
| Activities to Increase Compliance or Adherence | They were also provided with a homework booklet for  a job crafting exercise. During the two weeks between  the first and second sessions, they were encouraged to  implement their job crafting plans. | Participants were given homework booklets and encouraged to practice job crafting between sessions | TP |
| Intervention Delivery | Unit of Delivery | Groups of 9–13 participants | Groups of 9–13 participants | TP |
| Setting | Company meeting rooms and hospital rooms | Company meeting rooms and hospital rooms | TP |
| Time Span | Two weeks between sessions | Two weeks between sessions | TP |
| Intervention Deliverer | Researcher and clinical psychologist | First author (researcher) and one clinical psychologist | TP |
| Analysis | Unit of Analysis | Individual participant | Individual participant | TP |
| Recruitment | Setting | two private companies, hospital | Private manufacturing company and private psychiatric hospital in Japan | TP |
| Location | Japan | Tokyo, Japan | TN |
| Outcomes | Primary Outcome | Work engagement | Work engagement | TP |
| Secondary Outcome | Psychological distress, Job crafting | Job crafting and psychological distress | TP |
| Validated Instruments | Utrecht Work Engagement Scale (UWES), Psychological distress was measured using the Brief Job Stress Questionnaire (BJSQ), Job crafting was assessed using a scale developed by Sekiguchi and his colleagues [21] based on the conceptualization by Wrzesniewski and Dutton | Utrecht Work Engagement Scale (UWES); Brief Job Stress Questionnaire (BJSQ); Job crafting scale by Sekiguchi et al. | TP |
| Binding | Accomplishment | - | No blinding was performed | TN |
| Assignment | - | Open-label; participants and researchers knew about intervention | TN |
| Participation criteria | Min Age | Aver. 46,3 | 38 | FN |
| Max Age |  | 49 | FN |
| Eligibility Criteria | regular (full time) employment; | Full-time regular employment; workers with part-time or temporary reemployment excluded | TP |
| Number of participants |  |  |  |
| Sample | Sample Size | 50 | 50 | TP |
| Determination | an effect size (Cohen’s d) of 0.35 or greater for work engagement, at an alpha error rate of 0.05 (two-tailed) and  a beta error rate of 0.20 using the G\*Power 3 program  [34, 35]. | Estimated to detect effect size (Cohen’s d) of 0.35 or greater at alpha 0.05, beta 0.20 using G\*Power 3 | TP |
| Explanation Inherim Analyses and Stopping Rule | - | No interim checks or stopping rules were reported | TN |
| Statistical Methods | Primary Outcome Analysis | A linear mixed model for repeated measures conditional growth model analysis over time: a: random intercept and random slope; random intercept only; and random slope only. fixed model | StatisticalMethods hasDescription "Linear mixed model for repeated measures, t-tests, Cohen’s d effect sizes with 95% confidence intervals”  Analysis of work engagement change across timepoints using mixed model; effect sizes calculated with Cohen’s d | FP |
| Additional Analysis | - | Subgroup comparisons between departments and demographic characteristics at baseline | TN |
| Missing Data Handling | Dropout participants were excluded | Dropout participants were excluded from effect size analysis; handled by complete-case analysis | TP |
| Statistical Software | SPSS Statistics 22.0 | SPSS Statistics 22.0 | TP |
| Assignment Methods | Method to Assign Units to Study Conditions | - | All eligible participants in target departments invited; no randomization  Study conducted without a control group due to organizational constraints | TN |
| Unit of Assignment | Individuals | Individuals | TP |
| Restrictions | - | No assignment restrictions reported | TN |
| Bias Minimization Method | - | None stated; study acknowledged non-randomization as a limitation | TN |
| Other Methods | Methods to Account Variance |  | Mixed model for repeated measures analysis over time used to account for intra-individual variance | TN |
| Recruitment Methods | Participants were approached by a contact person in  their own company or hospital using an e-mail invitation  or a poster. | Participants were approached by a contact person in their own company or hospital using an e-mail invitation or a poster | TP |
| Sampling Methods | - | All full-time managers in a company and seven selected departments in a hospital were invited; not a systematic sampling plan | TN |
| Quality Enhancing Methods | Validated and standardized psychometric instruments used; ethics approval obtained | Validated and standardized psychometric instruments used; ethics approval obtained | TP |
| Data Collecting Methods | All data were collected using a web-based self-report  questionnaire at baseline, post-intervention, and onemonth follow-up. | Web-based self-report questionnaire at three timepoints: baseline, post-intervention, one-month follow-up | TP |
| Intervention Delivery Methods | Delivered in-person in group settings during or outside working hours | Delivered in-person in group settings during or outside working hours | TP |

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| Class | Attributes | Manual extraction | LLM extraction | TP, FP, FN |
| Study | Study Name | Extending research on Emotion Regulation Individual Therapy for Adolescents (ERITA) with nonsuicidal self-injury disorder: open pilot trial and mediation analysis of a novel online version | Extending research on ERITA with NSSID: open pilot trial | FP |
| Authors | Johan Bjureberg1\* , Hanna Sahlin1 , Erik Hedman-Lagerlöf2 , Kim L. Gratz3 , Matthew T. Tull3 , Jussi Jokinen1,4, Clara Hellner1 and Brjánn Ljótsson | Bjureberg et al. | FP |
| Publisher | BMC Psychiatry | BMC Psychiatry | TP |
| PublishDate | 11.10.2018 | 2018-10-25 | FP |
| Design | uncontrolled open trial | Uncontrolled open pilot trial | TP |
| Objective | examined the feasibility, acceptability, and utility of an online version of ERITA. | To examine feasibility, acceptability, and utility of an online version of ERITA in adolescents with NSSID. | TP |
| Hypothese | Online treatments carry the potential to increase the availability of evidence-based treatments. Emotion regulation individual therapy for adolescents (ERITA) has shown promise in the treatment of adolescents with NSSID. | Online ERITA would show high completion and satisfaction, and improvements in NSSI and emotion regulation. | TP |
| Interventions | Content | The adolescent treatment included 11 online modules adapted from the ERITA manual. 6 parents modules every other week.  Post-treatment and follow-up assessments were administered directly after treatment completion (i.e., 11 weeks after treatment start) and at 3 and 6 months post-treatment completion.  The treatment platform was completely web-based | Online version of ERITA for adolescents and parallel online parent program with therapist guidance. | TP |
| Exposure quantity | 11 | 11 | TP |
| Duration | 12 weeks | 12 weeks | TP |
| Activities to Increase Compliance or Adherence | The psychologist reviewed the participants’ responses and provided written feedback through the platform. In the case of participant inactivity, the psychologist reminded the participant through text messages or telephone calls. Further, the psychologist helped problem solve, guide participants through the program, and assist with the homework assignments when necessary. | Weekly therapist guidance, reminders via text/call in case of inactivity, homework support, app-based tracking. | TP |
| Intervention Delivery | Unit of Delivery | Individual adolescent and parent modules |  | FN |
| Setting | Web based platform |  | FN |
| Time Span | 12 weeks |  | FN |
| Intervention Deliverer | clinical psychologist |  | FN |
| Analysis | Unit of Analysis | Individual adolescent, parent | Individual | TP |
| Recruitment | Setting | Online, mental health services (CAMHS) | Child and Adolescent Mental Health Services (CAMHS), social media, local newspaper, national self-injury project website | TP |
| Location | Stockholm, Sweden | Stockholm, Sweden | TP |
| Outcomes | Primary Outcome | NSSI frequency reduction (DSHI-9) | Change in past-month NSSI frequency using DSHI-9 | TP |
| Secondary Outcome | 36-item Difficulties in Emotion Regulation Scale (DERS), 11-item behavior supplement to the Borderline Symptom List (BSL), Borderline Personality Feature Scale for Children (BPFS-C), 7-item Acceptance and Action Questionnaire (AAQ-II),  Children’s Global Assessment Scale (CGAS),  Children’s Negative Emotions Scale – Adolescent version (CCNES-A) | Emotion dysregulation (DERS), global functioning (CGAS), BPD symptoms (BPFS-C), psychological inflexibility (AAQ-II) | FP |
| Validated Instruments | DSHI-9, DERS, CGAS, BPFS-C, AAQ-II, BSL, CCNES-A | DSHI-9, DERS, DERS-16, CGAS, BPFS-C, AAQ-II, MINI-KID, NSSI Disorder Index, SCID-BPD | FP |
| Binding | Accomplishment | - | Not applicable due to open trial design. | TN |
| Assignment | - | Not blinded; open-label study. | TN |
| Participation criteria | Min Age | 13 | 13 | TP |
| Max Age | 17 | 17 | TP |
| Eligibility Criteria | inclusion criteria for the adolescents were: (a) 13–17 years of age; (b) meeting diagnostic criteria for NSSID [2]; (c) having engaged in ≥1 NSSI episode during the past month; (d) having at least one parent who committed to participate in the parent program; and (e) stability of psychotropic medications (if any) for at least 2 months. Exclusion criteria for the adolescents were: (f ) severe suicidal ideation; (g) a diagnosis of psychotic or bipolar I disorder or ongoing (past month) substance dependence; (h) ongoing dialectical behavioral therapy or mentalization-based treatment; and (i) insufficient understanding of the Swedish language. | 13–17 years of age; meeting diagnostic criteria for NSSID; ≥1 NSSI episode past month; parent participation; stable psychotropic meds if any. | FP |
| Number of participants |  |  |  |
| Sample | Sample Size | 25 | 25 | TP |
| Determination | - | Open trial, not based on power calculation. | TN |
| Explanation Inherim Analyses and Stopping Rule | - | No interim checks or stopping rules reported. | TN |
| Statistical Methods | Primary Outcome Analysis | Generalized estimation equations (GEE) with exchangeable working correlation structure along with robust error estimations were used to model change in outcome measures across the treatment and follow up periods | StatisticalMethods hasDescription: Used generalized estimation equations (GEE) with negative binomial and normal distributions; Cohen’s d effect size; bootstrapped confidence intervals.  Pre-post and follow-up changes in NSSI frequency and other measures assessed using GEE models; 55% reduction in NSSI observed. | FP |
| Additional Analysis | change in emotion regulation difficulties as a mediator of improvements in NSSI and self-destructive behaviors during treatment in two sets of mediation analyses – regression analysis | Mediation analysis: emotion regulation difficulties mediated improvements in NSSI and self-destructive behavior. | TP |
| Missing Data Handling | included regression weights in the GEE models that were inversely related to the probability of a value being observed as a function of time | Inverse probability weights used in GEE to handle missing data; assumed missing at random. | TP |
| Statistical Software | R version 3.3.1 | Analyses conducted using R version 3.3.1. | TP |
| Assignment Methods | Method to Assign Units to Study Conditions | - | method\_assignment hasDescription "Uncontrolled open trial; all eligible participants received the intervention.  No assignment to conditions; all participants received the intervention. | TN |
| Unit of Assignment | Individual adolescent, parent | Individual adolescents and their parents. | TP |
| Restrictions | - | None; no blocking or stratification. | TN |
| Bias Minimization Method | - | No matching or minimization used due to open trial design. | TN |
| Other Methods | Methods to Account Variance | - | Generalized estimation equations (GEE) with inverse probability weighting to handle missing data; robust error estimation. | TN |
| Recruitment Methods | Participants were self-referred via newspaper ads, social media, and national website or referred from CAMHS | Participants were self-referred or referred by CAMHS after clinics received information via email and internal web. | TP |
| Sampling Methods | eligibility screening | No systematic sampling plan; inclusion criteria applied to referred/self-referred volunteers. | FP |
| Quality Enhancing Methods | - | Validated instruments with strong psychometric properties; internal consistency reported. | TN |
| Data Collecting Methods | Weekly modules responses | Data collected via self-report, clinician interviews, and weekly digital assessments. | TP |
| Intervention Delivery Methods | Delivered entirely online via web platform and mobile app; weekly modules with asynchronous psychologist feedback. | Delivered via fully online platform with interactive modules and mobile app. | TP |

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| Class | Attributes | Manual extraction | LLM extraction | TP, FP, FN |
| Study | Study Name | Managing Cancer And Living Meaningfully (CALM): Phase 2 trial of a brief individual psychotherapy for patients with advanced cancer | Managing Cancer And Living Meaningfully (CALM): Phase 2 trial | FP |
| Authors | Chris Lo1,2, Sarah Hales1,2, Judy Jung1, Aubrey Chiu1, Tania Panday1, Anne Rydall1, Rinat Nissim1, Carmine Malfitano1, Danielle Petricone-Westwood1, Camilla Zimmermann1,2 and Gary Rodin1 | Chris Lo, Sarah Hales, Judy Jung, Aubrey Chiu, Tania Panday, Anne Rydall, Rinat Nissim, Carmine Malfitano, Danielle Petricone-Westwood, Camilla Zimmermann, Gary Rodin | TP |
| Publisher | Palliative Medicine | Palliative Medicine | TP |
| PublishDate | 10.2013 | 2013-10-01 | TP |
| Design | phase 2 intervention-only design | Phase 2 intervention-only design | TP |
| Objective | To test the feasibility and preliminary effectiveness of CALM to reduce emotional distress and promote psychological well-being and growth. | To test the feasibility and preliminary effectiveness of CALM to reduce emotional distress and promote psychological well-being and growth. | TP |
| Hypothese | there would be a reduction in depressive symptoms and death anxiety over time, and an increase in attachment security, spiritual well-being and psychological growth. | CALM would reduce depressive symptoms and death anxiety, and increase attachment security, spiritual well-being, and psychological growth. | TP |
| Interventions | Content | 3–8 individual sessions delivered over 6 months with each session lasting 60 min. The sessions address four domains: (1) symptom management and communication with health care providers; (2) changes in self and relations with close others; (3) spiritual well-being or the sense of meaning and purpose; and (4) preparing for the future, sustaining hope and facing mortality | CALM includes 3–8 individual sessions over 6 months, addressing symptom management, self-concept, spirituality, and future preparation. | TP |
| Exposure quantity | 3-8 | 3 | FP |
| Duration | 60 min | 60 minutes per session | TP |
| Activities to Increase Compliance or Adherence | primary caregiver (i.e. spouse or partner, adult son or daughter) is offered the opportunity to participate | Caregiver involvement encouraged; flexible scheduling; supervised therapists. | FP |
| Intervention Delivery | Unit of Delivery | Individual | Individual, with optional caregiver participation | TP |
| Setting | Princess Margaret Cancer Centre | Princess Margaret Cancer Centre, Toronto | TP |
| Time Span | 6 months | 3–8 sessions over 6 months | FP |
| Intervention Deliverer | six master’s level social workers, two psychiatrists, and one oncologist | Therapists (social workers, psychiatrists, oncologist) with training in CALM. | TP |
| Analysis | Unit of Analysis | Individual | Individual | TP |
| Recruitment | Setting | Princess Margaret Cancer Centre, part of the University Health Network | Medical and Psychosocial Oncology clinics | FP |
| Location | Toronto, Canada | Princess Margaret Cancer Centre, Toronto, Canada | TP |
| Outcomes | Primary Outcome | depressive symptoms | Depressive symptoms | TP |
| Secondary Outcome | death anxiety, attachment security, spiritual well-being and psychological growth | Death anxiety, attachment security, spiritual well-being, psychological growth | TP |
| Validated Instruments | PHQ-9, FACIT-Sp-12, DADDS, ECR-M16, PTGI | PHQ-9, FACIT-Sp-12, DADDS, ECR-M16, PTGI | TP |
| Binding | Accomplishment | - | No blinding conducted. | TN |
| Assignment | - | Not blinded; participants and therapists aware of intervention. | TN |
| Participation criteria | Min Age | 18 | 18 | TP |
| Max Age | - |  |  |
| Eligibility Criteria | confirmed diagnosis of Stage IV cancer, or Stage III lung cancer; did not have cognitive impairment documented in their medical chart; were sufficiently fluent in English to provide informed consent and to participate in the intervention; and were interested in individual psychotherapy to assist in their coping with disease | Stage IV cancer or Stage III lung cancer; no cognitive impairment; fluent in English; interested in individual psychotherapy. | TP |
| Number of participants |  |  |  |
| Sample | Sample Size | 50 | 50 | TP |
| Determination | written informed consent from those who agreed to participate | Participants were recruited from clinics, 141 approached, 50 consented. | FP |
| Explanation Inherim Analyses and Stopping Rule | - | Not reported. | TN |
| Statistical Methods | Primary Outcome Analysis | multilevel modelling55 was used to predict the trajectory of each variable as a function of the number of months since the start of CALM therapy | Multilevel regression was used to model change in depressive symptoms over time. | TP |
| Additional Analysis | - | Sub-analysis for patients with at least three CALM sessions. | TN |
| Missing Data Handling | Multilevel models accommodate missing data | Multilevel models accommodate missing data; no imputation reported. | TP |
| Statistical Software | - | Statistical analysis was performed using multilevel modeling; specific software not named. | TN |
| Assignment Methods | Method to Assign Units to Study Conditions | - | No randomization; all participants received the intervention (intervention-only design). | TN |
| Unit of Assignment | Individual | Individual | TP |
| Restrictions | - | Not applicable due to lack of randomization. | TN |
| Bias Minimization Method | - | Not reported; selection bias may be present due to self-selection and nonrandomized design. | TN |
| Other Methods | Methods to Account Variance |  | Multilevel regression used to model change and account for variation between and within participants. | TN |
| Recruitment Methods | routine visits to clinics | Patients were approached during routine clinic visits by research assistants. | TP |
| Sampling Methods | - | No systematic sampling method described; convenience sampling implied. | TN |
| Quality Enhancing Methods | Validated instruments with established psychometric properties used. | Validated instruments with established psychometric properties used. | TP |
| Data Collecting Methods | self-report questionnaires administered at baseline, 3 months, and 6 months. | self-report questionnaires administered at baseline, 3 months, and 6 months. | TP |
| Intervention Delivery Methods | Delivered in person as individual sessions by trained therapists. | Delivered in person as individual sessions by trained therapists. | TP |

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| Class | Attributes | Manual extraction | LLM extraction | TP, FP, FN |
| Study | Study Name | Family-Centered Care Improves Clinical Outcomes of Very-Low-Birth-Weight Infants | Family-Centered Care Improves Clinical Outcomes of Very-Low-Birth-Weight Infants | TP |
| Authors | Bo Lv 1†, Xi-ronga Gao1†, Jing Sun2 , Tao-tao Li 1 , Zhen-ye Liu1 , Li-hui Zhu3 \* and Jos M. Latour 3, | Bo Lv, Xi-ronga Gao, Jing Sun, Tao-tao Li, Zhen-ye Liu, Li-hui Zhu, Jos M. Latour | TP |
| Publisher | Frontiers in Pediatrics | Frontiers in Pediatrics | TP |
| PublishDate | 2019-04-12 | 2019-04-12 | TP |
| Design | quasi-experimental study | Quasi-experimental study using convenience sampling | TP |
| Objective | to implement and test an FCC intervention providing parental education and participation in care among parents with VLBW infants. | To evaluate a family-centered care intervention on clinical outcomes of very-low-birth-weight infants | FP |
| Hypothese | parent education and parent participation in care improve clinical outcomes of VLBW infants. | Parent education and parent participation in care improve clinical outcomes of VLBW infants | TP |
| Interventions | Content | Parental education on basic care, infant development, hand hygiene, feeding methods, skin-to-skin contact, infection control | Parental education on infant care, hand hygiene, breastfeeding, skin-to-skin contact; parents performed basic care activities and participated in care for at least 4 h/day. | TP |
| Exposure quantity | - | 1 | TN |
| Duration | From admission until discharge | From admission until discharge | TP |
| Activities to Increase Compliance or Adherence | Ongoing nurse support | Ongoing nurse support and skill assessments before parental involvement. | TP |
| Intervention Delivery | Unit of Delivery | Individual | Individual (parent-infant dyad) | TP |
| Setting | Hunan Children’s Hospital | Level 3 NICU, Hunan Children's Hospital | TP |
| Time Span | June 2016 to June 2017 | June 2016 to June 2017 | TP |
| Intervention Deliverer | NICU nurses | NICU nurses trained in FCC methods | TP |
| Analysis | Unit of Analysis | Individual infant | Individual infant | TP |
| Recruitment | Setting | Hunan Children’s Hospital | Level 3 NICU at Hunan Children’s Hospital, China | TP |
| Location | Changsha, China | Changsha, China | TP |
| Outcomes | Primary Outcome | weight at discharge, NICU length-of-stay, breastfeeding rate, days of nasal feeding, days of total parental nutrition, re-admission within 1 month, hospital expenses | Infant weight at discharge; breastfeeding rate; days of total parenteral nutrition; days of nasal feeding. | FP |
| Secondary Outcome | nosocomial infection rate, Bronchopulmonary dysplasia (BPD), Retinopathy of prematurity (ROP), Necrotizing enterocolitis (NEC), Intraventricular hemorrhage (IVH). | Length of NICU stay; hospital expenses; complications: BPD, ROP, NEC, IVH, nosocomial infection, re-admission within 1 month. | FP |
| Validated Instruments | - |  |  |
| Binding | Accomplishment | blinding was not possible | Blinding was not possible due to the nature of nurse-led education and care. | TP |
| Assignment | - | Neither parents nor staff were blinded to group assignment. | TN |
| Participation criteria | Min Age | - | 0 |  |
| Max Age | - | 0 |  |
| Eligibility Criteria | Inclusion criteria were: preterm infants with a birth weight <1,500 g; non-invasive oxygen support; parents willing to participate in the care for at least 4 h a day. Exclusion criteria  were: Infants with life-threatening congenital anomalies; surgery; palliative care; expected discharge within 1 week. | Preterm infants with birth weight <1,500 g; non-invasive oxygen support; parents willing to participate in the care for at least 4 h a day. Exclusion: life-threatening congenital anomalies, surgery, palliative care, expected discharge within 1 week. | TP |
| Number of participants |  |  |  |
| Sample | Sample Size | 319 | 319 | TP |
| Determination | 12-month recruitment period using convenience sampling | Sample size was determined based on 12-month recruitment period using convenience sampling. | TP |
| Explanation Inherim Analyses and Stopping Rule | - |  |  |
| Statistical Methods | Primary Outcome Analysis | Kolmogorov-Smirnow test was used to determine normal distribution of data, mean, standard deviation percentages were applied. The Student t-test was used for continuous variable and the chi-square test for categorical variable | Kolmogorov-Smirnov test for normality; Student t-test for continuous variables; chi-square test for categorical variables; p < 0.05 considered significant. | TP |
| Additional Analysis | - |  |  |
| Missing Data Handling | - |  |  |
| Statistical Software | IBM SPSS Statistics for Windows, Version 21.0 | IBM SPSS Statistics for Windows, Version 21.0 | TP |
| Assignment Methods | Method to Assign Units to Study Conditions | First admitted infant assigned to intervention, second to control, alternating thereafter. | First admitted infant assigned to intervention, second to control, alternating thereafter. | TP |
| Unit of Assignment | Individual infants (VLBW neonates) | Individual infants (VLBW neonates) | TP |
| Restrictions | - | No blinding possible due to nature of intervention. | TN |
| Bias Minimization Method | - | Not explicitly mentioned. | TN |
| Other Methods | Methods to Account Variance | - | Not explicitly discussed. | TN |
| Recruitment Methods | Infants and parents were recruited and assigned upon admission. At the start of the study, the first infant was recruited and assigned to the intervention group, the second infant to the control group and further recruitment took place in subsequent order. | Infants and parents were recruited upon admission using alternating assignment into intervention and control groups. | TP |
| Sampling Methods | convenience sampling | Convenience sampling over 12-month period. | TP |
| Quality Enhancing Methods | Nurses trained before delivering FCC; theoretical teaching standardized. | Nurses trained before delivering FCC; theoretical teaching standardized. | TP |
| Data Collecting Methods | extracted from the infant’s hospital records, Basic demographics of parents (mode of delivery, education and income levels) were collected | Infant health data collected from hospital records; parental demographics collected on admission. | TP |
| Intervention Delivery Methods | In-person education and care sessions during NICU admission, 4 h/day parental involvement | In-person education and care sessions during NICU admission, 4 h/day parental involvement | TP |

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| Class | Attributes | Manual extraction | LLM extraction | TP, FP, FN |
| Study | Study Name | An authentic leadership training programme to increase nurse empowerment and patient safety: A quasi-experimental study | An authentic leadership training programme to increase nurse empowerment and patient safety | TP |
| Authors | Hasan Fehmi Dirik | Seyda Seren Intepeler | Hasan Fehmi Dirik, Seyda Seren Intepeler | TP |
| Publisher | Journal of Advanced Nursing | Journal of Advanced Nursing | TP |
| PublishDate | 2024-04 | 2024-04-01 | TP |
| Design | A quasi-experimental study using a one-group pretest–posttest | Quasi-experimental study using a one-group pretest–posttest design | TP |
| Objective | to investigate the impact of an educational intervention delivered through a multi-faceted training programme on nurses' perceptions of authentic leadership, nurse empowerment (both structural and psychological) and the patient safety climate. | To investigate the impact of an educational intervention delivered through a multi-faceted training programme on nurses' perceptions of authentic leadership, nurse empowerment and the patient safety climate. | TP |
| Hypothese | 1. Nurses' perceptions of head nurses' authentic leadership predict safety climate. 2. Nurses' perceptions of structural empowerment predict safety climate. 3. Nurses' perceptions of psychological empowerment predict safety climate. | 1. Nurses' perceptions of head nurses' authentic leadership predict safety climate. 2. Nurses' perceptions of structural empowerment predict safety climate. 3. Nurses' perceptions of psychological empowerment predict safety climate. | TP |
| Interventions | Content | Multi-faceted training programme with 10 main sessions and 3 reinforcement sessions focused on authentic leadership, empowerment, and patient safety. | Multi-faceted training programme with 10 main sessions and 3 reinforcement sessions focused on authentic leadership, empowerment, and patient safety. | TP |
| Exposure quantity | 13 | 13 | TP |
| Duration | 45 min | 3 months + 6 months follow-up | FP |
| Activities to Increase Compliance or Adherence | a booklet containing extra exercises to increase the participants' interest and to guide them. Finally, we gave a keychain designed with images of the programme themes as a memento and reminder of the principles of authentic leadership, empowerment and patient safety. | Follow-up sessions, interviews, extra exercises booklet, symbolic keychain as a memento. | TP |
| Intervention Delivery | Unit of Delivery | Group format, 3 groups of 12 head nurses | Group format, 3 groups of 12 head nurses | TP |
| Setting | the training room of the hospital and an additional three reinforcement sessions in the units. | Training room of the university hospital and participants’ units | TP |
| Time Span | 9 months | 9 months total (3 months training + 6 months reinforcement) | TP |
| Intervention Deliverer | Researchers | Researchers (Hasan Fehmi Dirik and Seyda Seren Intepeler) | TP |
| Analysis | Unit of Analysis | Individual head nurses and individual nurse followers | Individual head nurses and individual nurse followers | TP |
| Recruitment | Setting | university hospital | University hospital with 55 units and 1000 bed capacity in Aegean region of Turkey | TP |
| Location | Turkey | Izmir, Turkey | FP |
| Outcomes | Primary Outcome | safety climate and authentic leadership | Improvement in perception of patient safety climate and authentic leadership. | TP |
| Secondary Outcome | Structural and psychological empowerment | Structural and psychological empowerment of nurses. | TP |
| Validated Instruments | Safety Climate Survey (SCS), Authentic Leadership Questionnaire (ALQ), Conditions of Work Effectiveness Questionnaire-II (CWEQ-II), Psychological Empowerment Instrument (PEI). | Safety Climate Survey (SCS), Authentic Leadership Questionnaire (ALQ), Conditions of Work Effectiveness Questionnaire-II (CWEQ-II), Psychological Empowerment Instrument (PEI). | TP |
| Binding | Accomplishment | - |  |  |
| Assignment | - | No blinding; all participants and researchers were aware of the intervention. | TN |
| Participation criteria | Min Age | Aver. 43,8 | 36 | TN |
| Max Age |  | 44 | TN |
| Eligibility Criteria | nurse leaders (head nurses) with at least 6 months of managerial experience who had not previously attended a leadership programme. The exclusion criterion was anyone who was either unwilling/unable to participate or did not complete the training sessions that were part of the intervention. nurses who worked under the 36 head nurses | Head nurses with at least 6 months managerial experience, not previously in leadership programme; followers were nurses reporting to those leaders. | TP |
| Number of participants | - |  |  |
| Sample | Sample Size | 189 | 189 | TP |
| Determination | Convenience sample of 36 head nurses and 153 followers. | Convenience sample of 36 head nurses and 153 followers. | TP |
| Explanation Inherim Analyses and Stopping Rule | - | Not reported. | TN |
|  |  |  | ex:Methods001 a ex:Methods ; ex:hasDescription "Multi-faceted intervention design based on TREND guidelines with three phases: education, reinforcement, and evaluation. Included in-person training and follow-up." |  |
| Statistical Methods | Primary Outcome Analysis | descriptive statistics of demographic and work-related characteristics, analysis of variance for the head nurses, t-tests for the followers. Bonferroni correction for the post hoc analyses | Repeated measures ANOVA and dependent samples t-tests used to evaluate change in safety climate and leadership scores over time. | FP |
| Additional Analysis | hierarchical regression analysis to test our prediction | Hierarchical regression models tested predictive value of authentic leadership and empowerment on safety climate. | TP |
| Missing Data Handling | Responses to the option ‘I have no idea/comment’ were not included in the calculations. | Responses with 'I have no idea/comment' were excluded from analysis. No imputation reported. | TP |
| Statistical Software | Statistical Package for the Social Sciences (SPSS) 22.0 | SPSS 22.0 used for statistical analysis. | TP |
| Assignment Methods | Method to Assign Units to Study Conditions | One-group pretest-posttest design | One-group pretest-posttest design; no assignment to different groups. | TP |
| Unit of Assignment | Head nurses and their followers | Head nurses and their followers (groups defined by reporting structure) | TP |
| Restrictions | - | No specific restrictions reported. | TN |
| Bias Minimization Method | - | TREND guideline applied; no randomization, but design attempted to minimize bias by including all eligible head nurses. | TN |
| Other Methods | Methods to Account Variance | - | Used repeated measures ANOVA and hierarchical regression analysis to account for pre-post changes and confounders. | TN |
| Recruitment Methods | Invitation sent to eligible head nurses. Followers recruited from nurses working under participating head nurses. | Invitation sent to eligible head nurses. Followers recruited from nurses working under participating head nurses. | TP |
| Sampling Methods | convenience sample | Convenience sampling; 36 head nurses and their 153 followers. | TP |
| Quality Enhancing Methods | ? | Use of validated instruments with high reliability scores. Data collected in sealed envelopes by trained researchers. | TP |
| Data Collecting Methods | Surveys administered before, immediately after, and 6 months after intervention. Distributed and collected in person. | Surveys administered before, immediately after, and 6 months after intervention. Distributed and collected in person. | TP |
| Intervention Delivery Methods | In-person workshops, station exercises, group work, Q&A, case studies, follow-up sessions in work units. | In-person workshops, station exercises, group work, Q&A, case studies, follow-up sessions in work units. | TP |

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| Class | Attributes | Manual extraction | LLM extraction | TP, FP, FN |
| Study | Study Name | Exploring a parent-focused physical literacy intervention for early childhood: a pragmatic controlled trial of the PLAYshop | Exploring a parent-focused physical literacy intervention for early childhood: a pragmatic controlled trial of the PLAYshop | TP |
| Authors | Cassandra Lane1,2, Patti‑Jean Naylor3 , Madison Predy4 , Mette Kurtzhals5 , Ryan E. Rhodes3 , Kayla Morton3 , Stephen Hunter4 and Valerie Carson | Cassandra Lane, Patti‑Jean Naylor, Madison Predy, Mette Kurtzhals, Ryan E. Rhodes, Kayla Morton, Stephen Hunter, Valerie Carson | TP |
| Publisher | BMC Public Health | BMC Public Health | TP |
| PublishDate | 05.04.2022 | 2022-04-11 | FP |
| Design | pragmatic controlled trial | pragmatic controlled trial; type 1 effectiveness-implementation hybrid | TP |
| Objective | to evaluate the preliminary efcacy of  a theory-based, feasible and potentially scalable physical  literacy intervention for parents of preschool-aged children (aged 3-5years) | To evaluate the preliminary efficacy of a theory-based, feasible and potentially scalable physical literacy intervention (the PLAYshop) for parents of preschool-aged children. | TP |
| Hypothese | parents in the intervention group will have a larger increase in levels of knowledge and confdence in regards to engaging in meaningful play with their preschool child(ren) than parents in the control group.  parents will report satisfaction with the implementation and change parenting practices related to physical activity at 2-month follow-up. | Parents in the intervention group will report higher knowledge and confidence, and will show improved parenting practices in facilitating children's physical literacy development, compared to control group. | FP |
| Interventions | Content | 75-min inperson workshop during which trained leaders provided parents and their child with physical literacy education and experiential learning | 75-min in-person PLAYshop workshop with interactive activities and educational messages; educational materials; equipment pack; two post-workshop booster emails. | TP |
| Exposure quantity | 1 | 1 | TP |
| Duration | 75 min | 4 months (November 2019 – March 2020) | FP |
| Activities to Increase Compliance or Adherence | post-workshop booster emails | Booster emails sent at weeks 3 and 6; included key messages and follow-up support. | TP |
| Intervention Delivery | Unit of Delivery | Group-based workshop sessions for parents and children | Group-based workshop sessions for parents and children | TP |
| Setting | Community sites | Community sites such as recreation centers and sport clubs | TP |
| Time Span | November 2019 – March 2020 | 75-minute workshop, follow-up over 2 months | TP |
| Intervention Deliverer | trained leaders | Trained facilitators with background in physical literacy, following structured protocol | TP |
| Analysis | Unit of Analysis | Parent participant | Parent participant | TP |
| Recruitment | Setting | informational posters placed in community  recreation centers, daycare centers, and preschools (AB  & BC); Facebook and Twitter posts (AB & BC); posters  attached within a local electronic newsletter (AB); and  posters emailed to parent playgroups (BC). | Community recreation centers, daycare centers, preschools, social media (Facebook/Twitter), newsletters, parent playgroups | TP |
| Location | Canadian cities of Edmonton, Alberta (AB) and Victoria, British Columbia (BC) | Edmonton, Alberta and Victoria, British Columbia, Canada | TP |
| Outcomes | Primary Outcome | parents’ selfreported knowledge and confdence assessed at baseline and follow-up | Change in parents’ self-reported knowledge and confidence related to physical literacy | TP |
| Secondary Outcome | Parent-reported changes in parenting practices related to physical literacy facilitation; implementation facilitators and barriers | Parent-reported changes in parenting practices related to physical literacy facilitation; implementation facilitators and barriers | TP |
| Validated Instruments | psychometrically validated physical activity parenting practices (PAPP) item bank | Validated Likert-scale instruments with high Cronbach alpha; ACTS-MG and PAPP item banks used. | TP |
| Binding | Accomplishment | Not fully accomplished; intervention deliverers were not blinded. | Not fully accomplished; intervention deliverers were not blinded. | TP |
| Assignment | Participants were blinded to group assignment however allocation concealment was not performed for those delivering the intervention due to limited resources (i.e., staf) | Participants were blinded to group assignment; allocation concealment not performed for staff due to resource constraints. | TP |
| Participation criteria | Min Age | Aver. 37 | 3 | FP |
| Max Age |  | 5 | FP |
| Eligibility Criteria | Eligible parents had to live within a workshop delivery area and have at least one child aged 3-5years. | Parents living within workshop delivery area and having at least one child aged 3–5 years. | TP |
| Number of participants |  |  |  |
| Sample | Sample Size | 143 | 143 | TP |
| Determination | Te initial sample size was set at a total of 100 parents (50 control and 50 intervention), providing an estimated 0.80 power for a medium to large efect size with alpha set at 0.05 for a t-test between two independent means. | Initial sample size target was 100 to achieve 0.80 power for medium-large effect size; final N=143 | TP |
| Explanation Inherim Analyses and Stopping Rule | - | Not reported. | TN |
| Statistical Methods | Primary Outcome Analysis | Descriptive statistics were generated for all outcome measures and one-way ANOVA was used to determine if there were any signifcant diferences between the groups in baseline characteristics. | Repeated measures ANOVA on parents' self-reported knowledge and confidence using validated scales. | TP |
| Additional Analysis | Exploration of group-by-time interaction | Exploration of group-by-time interaction for secondary outcomes including perceived barriers and resource availability. | TP |
| Missing Data Handling | - | Incomplete responses due to COVID-related cancellations; descriptive statistics reported; no imputation described. | TN |
| Statistical Software | SPSS Version 21.0 | SPSS Version 21.0 used for all quantitative data analysis. | TP |
| Assignment Methods | Method to Assign Units to Study Conditions | BC participants were randomly assigned using a computer-generated 1:1 sequence and parents were provided with two choices for intervention workshop times; AB participants were systematically assigned using an alternating sequence as they enrolled and were provided with a list of workshop dates to choose from. | Random assignment (computer-generated) in BC; systematic alternating sequence in AB. | TP |
| Unit of Assignment | Individual parent participants | Individual parent participants | TP |
| Restrictions | - | No formal restriction reported; assignment balanced groups pragmatically. | TN |
| Bias Minimization Method | Blinding of participants | Blinding of participants; use of standardized program plan for fidelity; limited staff resources prevented full allocation concealment. | TP |
| Other Methods | Methods to Account Variance | Repeated measures ANOVA used to test group-by-time effects; | Repeated measures ANOVA used to test group-by-time effects; effect sizes reported as partial eta squared. | TP |
| Recruitment Methods | Participants were recruited via posters, social media posts, and email outreach to parent groups. | Participants were recruited via posters, social media posts, and email outreach to parent groups. | TP |
| Sampling Methods | Systematic assignment (alternating sequence in AB); random assignment (computer-generated 1:1 in BC) | Systematic assignment (alternating sequence in AB); random assignment (computer-generated 1:1 in BC) | TP |
| Quality Enhancing Methods | ? | Used psychometrically validated items and reliability-tested scales. | TP |
| Data Collecting Methods | paper surveys in-person, immediately before and after their participation in the workshop. Participants in the control group completed online surveys a minimum of seven days apart prior to workshop attendance using a REDCap® [48] personalized link sent via email | Data collected via paper and online surveys; follow-up interviews; NVivo used for qualitative coding. | TP |
| Intervention Delivery Methods | Delivered in-person in workshop settings using active play, parent-child interaction, and distributed educational resources. | Delivered in-person in workshop settings using active play, parent-child interaction, and distributed educational resources. | TP |

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| Class | Attributes | Manual extraction | LLM extraction | TP, FP, FN |
| Study | Study Name |  | Effectiveness of a group intervention using pain neuroscience education and exercise in women with fibromyalgia |  |
| Authors |  | Paula B. Areso-Bóveda, Julia Mambrillas-Varela, Bárbara García-Gómez, José Ignacio Moscosio-Cuevas, Jesús González-Lama, Eva Arnaiz-Rodríguez, María Begoña Arroyo del Barco, Pilar San Teodoro-Blanco |  |
| Publisher |  | BMC Musculoskeletal Disorders |  |
| PublishDate |  | 2022-03-29 |  |
| Design |  | Pragmatic nonrandomised controlled trial |  |
| Objective |  | To explore the efficacy in fibromyalgia of an intervention based on pain neuroscience education and exercise compared to treatment as usual. |  |
| Hypothese |  |  |  |
| Interventions | Content |  | Pain neuroscience education (PNE) and body awareness exercises including breathing, proprioception, flexibility, strength and games. |  |
| Exposure quantity |  | 7 |  |
| Duration |  | 2 hours per session |  |
| Activities to Increase Compliance or Adherence |  | Active listening interview, printed summaries and educational material, group discussion, games and engaging language to avoid nocebo effects. |  |
| Intervention Delivery | Unit of Delivery |  | Group format, 9–13 participants |  |
| Setting |  | Primary care physiotherapy units in Burgos, Spain |  |
| Time Span |  | 6 weeks + 1 follow-up session at 1 month |  |
| Intervention Deliverer |  | Physiotherapists, Family Doctors, and Nurses |  |
| Analysis | Unit of Analysis |  | Individual |  |
| Recruitment | Setting |  | 5 urban health centres in Burgos and the Burgos Centro Physiotherapy Unit |  |
| Location |  | Burgos, Spain |  |
| Outcomes | Primary Outcome |  | FIQ total score reduction ≥20% and ≥50%; proportion with FIQ < 39; negativization of ACR 2010 FM criteria. |  |
| Secondary Outcome |  | Changes in PCS, HAD, BPI, HAQ scores; pain intensity; symptom severity; functional capacity. |  |
| Validated Instruments |  | S-FIQ, PCS (Pain Catastrophizing Scale), HAD (Hospital Anxiety and Depression Scale), BPI-sf (Brief Pain Inventory), HAQ (Health Assessment Questionnaire) |  |
| Binding | Accomplishment |  | No blinding possible due to nature of intervention; participants and facilitators aware of group assignments. |  |
| Assignment |  | Open-label study; no blinding of participants, deliverers, or outcome assessors. |  |
| Participation criteria | Min Age |  | 18 |  |
| Max Age |  | 75 |  |
| Eligibility Criteria |  | Women aged 18 or older, meeting ACR 2010 diagnostic criteria for FM; exclusions included incapacitating mental illness or intellectual disability. |  |
| Number of participants |  |  |  |
| Sample | Sample Size |  | 53 |  |
| Determination |  | No formal sample size calculation due to pragmatic and feasibility nature of the study; all eligible referred patients were included. |  |
| Explanation Inherim Analyses and Stopping Rule |  | No interim analysis or stopping rules applied. |  |
|  |  |  | ex:methods08 a ex:Methods ; ex:hasDescription "Intervention group received a 60–90 min individual interview and 6 weekly group sessions based on pain neuroscience education (PNE), followed by one review session a month later, including movement and exercise components." |  |
| Statistical Methods | Primary Outcome Analysis |  | Changes in Fibromyalgia Impact Questionnaire (FIQ) scores at 1 year were primary outcome, analyzed using ANCOVA adjusted for baseline and age. |  |
| Additional Analysis |  | Changes in anxiety, depression, pain intensity, and functional capacity using validated scales (e.g., HAD, BPI, HAQ) were analyzed between groups. |  |
| Missing Data Handling |  | Analysis was conducted on a per protocol basis; no specific missing data imputation was described. |  |
| Statistical Software |  | Data analysis performed using SPSS v24. |  |
| Assignment Methods | Method to Assign Units to Study Conditions |  | Participants assigned to intervention or control group based on availability to attend sessions. |  |
| Unit of Assignment |  | Individual participant. |  |
| Restrictions |  | No restrictions applied to assignment. |  |
| Bias Minimization Method |  | Baseline and age adjustments used in statistical analysis to account for group differences. |  |
| Other Methods | Methods to Account Variance |  | Analysis of covariance (ANCOVA) was used to adjust for baseline values and age. |  |
| Recruitment Methods |  | Patients referred from Primary Care Centres who met ACR 2010 criteria for FM; participation based on availability. |  |
| Sampling Methods |  | Opportunistic (non-probability) sampling of accessible FM patients in Primary Care. |  |
| Quality Enhancing Methods |  | se of validated Spanish versions of outcome questionnaires; standard session protocols. |  |
| Data Collecting Methods |  | Self-administered questionnaires at baseline and 1-year follow-up. |  |
| Intervention Delivery Methods |  | Delivered as face-to-face group sessions supported by PowerPoint presentations and physical activities led by healthcare professionals. |  |

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| Class | Attributes | Manual extraction | LLM extraction | TP, FP, FN |
| Study | Study Name |  | Emotion regulation individual therapy for adolescents with nonsuicidal self-injury disorder: a feasibility study |  |
| Authors |  | Johan Bjureberg, Hanna Sahlin, Clara Hellner, Erik Hedman-Lagerlöf, Kim L. Gratz, Jonas Bjärehed, Jussi Jokinen, Matthew T. Tull, Brjánn Ljótsson |  |
| Publisher |  | BMC Psychiatry |  |
| PublishDate |  | 2017-01-01 |  |
| Design |  | Uncontrolled open trial |  |
| Objective |  | To evaluate the feasibility, acceptability, and utility of Emotion Regulation Individual Therapy for Adolescents (ERITA) with Nonsuicidal Self-Injury Disorder (NSSID). |  |
| Hypothese |  | That ERITA would demonstrate high credibility and acceptability and lead to improvements in NSSI, self-destructive behaviors, emotion regulation difficulties, and BPD symptoms. |  |
| Interventions | Content |  | Emotion Regulation Individual Therapy for Adolescents (ERITA), adapted from ERGT manual; 12 weekly sessions; included modules on emotional awareness, regulation, and valued directions; combined with an internet-delivered parent program. |  |
| Exposure quantity |  | 12 |  |
| Duration |  | 12 weeks |  |
| Activities to Increase Compliance or Adherence |  | Parent involvement, youth-friendly design, online therapist support, simplified homework, relapse prevention session. |  |
| Intervention Delivery | Unit of Delivery |  |  |  |
| Setting |  |  |  |
| Time Span |  |  |  |
| Intervention Deliverer |  |  |  |
| Analysis | Unit of Analysis |  | Individual participant |  |
| Recruitment | Setting |  | Child and Adolescent Mental Health Services clinics |  |
| Location |  | Stockholm and Malmö, Sweden |  |
| Outcomes | Primary Outcome |  | Reduction in frequency and versatility of nonsuicidal self-injury (NSSI) |  |
| Secondary Outcome |  | Improvements in emotion regulation difficulties, borderline personality features, global functioning, and self-destructive behaviors |  |
| Validated Instruments |  | Deliberate Self Harm Inventory (DSHI-9), Difficulties in Emotion Regulation Scale (DERS), Borderline Personality Feature Scale for Children (BPFS-C), Children’s Global Assessment Scale (CGAS), Borderline Symptom List (BSL) |  |
| Binding | Accomplishment |  | Not applicable; open trial |  |
| Assignment |  | No blinding; open label design. |  |
| Participation criteria | Min Age |  | 13 |  |
| Max Age |  | 17 |  |
| Eligibility Criteria |  | 13–17 years old; met diagnostic criteria for NSSID; ≥1 NSSI episode in the past month; stable medication; ongoing psychiatric treatment; parental consent for parent program participation. Excluded: psychosis, bipolar I, substance dependence, severe anorexia, insufficient Swedish. |  |
| Number of participants |  |  |  |
| Sample | Sample Size |  | 17 |  |
| Determination |  | Participants were consecutively referred and screened from outpatient clinics; not randomized. |  |
| Explanation Inherim Analyses and Stopping Rule |  | No formal interim analyses or stopping rules reported. |  |
| Statistical Methods | Primary Outcome Analysis |  | Generalized Estimation Equation (GEE) models used for pre-post and follow-up comparisons; negative binomial and normal distributions applied depending on variable type. |  |
| Additional Analysis |  | Exploratory mediation analysis tested emotion regulation difficulties as mediator; interaction effects of concurrent treatment and medication explored. |  |
| Missing Data Handling |  | Handled using regression weights assuming missing at random; robust error estimation employed. |  |
| Statistical Software |  | R version 3.3.1 used for data analysis. |  |
| Assignment Methods | Method to Assign Units to Study Conditions |  | No random assignment; open, uncontrolled design. |  |
| Unit of Assignment |  | Individual adolescent participants. |  |
| Restrictions |  | No restrictions applied; no stratification or blocking. |  |
| Bias Minimization Method |  | No specific bias minimization methods used due to nonrandomized design. |  |
| Other Methods | Methods to Account Variance |  | Modeling included clustered bootstrapping and accounted for repeated measures within participants. |  |
| Recruitment Methods |  | Referral from outpatient mental health services  Referral-based recruitment from outpatient mental health clinics. |  |
| Sampling Methods |  | Consecutive sampling from eligible referrals.  Consecutive sampling without randomization. |  |
| Quality Enhancing Methods |  | Validated outcome measures; supervised assessments by trained clinicians; filmed sessions for fidelity. |  |
| Data Collecting Methods |  | Self-report questionnaires and clinician-rated interviews collected at pre-treatment, post-treatment, and 6-month follow-up. |  |
| Intervention Delivery Methods |  | Delivered in-person individually; supported by an online component for parents with therapist guidance. |  |

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| Class | Attributes | Manual extraction | LLM extraction | TP, FP, FN |
| Study | Study Name |  | Emergency Department Vestibular Rehabilitation Therapy for Dizziness and Vertigo |  |
| Authors |  | Howard S. Kim et al. |  |
| Publisher |  | JAMA Network Open |  |
| PublishDate |  | 2025-02-14 |  |
| Design |  | Nonrandomized clinical trial |  |
| Objective |  | To examine the feasibility of ED vestibular rehabilitation therapy (ED-VeRT) using a protocolized diagnostic classification algorithm and collection of longitudinal patient-reported outcomes. |  |
| Hypothese |  |  |  |
| Interventions | Content |  | ED-VeRT intervention consisting of evaluation and treatment based on diagnostic algorithm (e.g., Epley maneuver, glucocorticoids), education, and referral. |  |
| Exposure quantity |  | 1 |  |
| Duration |  | Single ED visit session with 3-month follow-up |  |
| Activities to Increase Compliance or Adherence |  | Participants received $10 gift card for each follow-up survey, up to $50. |  |
| Intervention Delivery | Unit of Delivery |  | Individual patient |  |
| Setting |  | Emergency Department |  |
| Time Span |  | November 16, 2021 to February 6, 2023 (follow-up to May 1, 2023) |  |
| Intervention Deliverer |  | ED Physical Therapists at Northwestern Memorial Hospital |  |
| Analysis | Unit of Analysis |  | Individual participant |  |
| Recruitment | Setting |  | Urban academic emergency department in Chicago, IL |  |
| Location |  | Northwestern Memorial Hospital |  |
| Outcomes | Primary Outcome |  | Change in Dizziness Handicap Inventory (DHI) score at 3 months. |  |
| Secondary Outcome |  | Change in Vestibular Activities Avoidance Inventory-9 (VAAI-9), use of sedating medication, follow-up care, and falls. |  |
| Validated Instruments |  | DHI (25-item scale, score 0-100), VAAI-9 (9-item scale, score 0-54) |  |
| Binding | Accomplishment |  | Not applicable; no blinding was used. |  |
| Assignment |  | Patients and physicians were not blinded due to discretionary treatment assignment. |  |
| Participation criteria | Min Age |  | 18 |  |
| Max Age |  | 99 |  |
| Eligibility Criteria |  | Inclusion: Age ≥18, presenting with isolated dizziness or vertigo. Exclusion: Severe neurologic deficit, non-English speakers, pregnancy, inability to follow up. |  |
| Number of participants |  |  |  |
| Sample | Sample Size |  | 125 |  |
| Determination |  | Initial target sample of 100 based on feasibility considerations; increased to 125 to account for ~20% attrition. |  |
| Explanation Inherim Analyses and Stopping Rule |  | No interim checks or stopping rules were applied. |  |
|  |  |  | ex:methods001 a ex:Methods ; ex:hasDescription "Participants received either the ED-VeRT intervention or usual care based on physician discretion. ED-VeRT was delivered by ED physical therapists using a standardized diagnostic and treatment algorithm." |  |
| Statistical Methods | Primary Outcome Analysis |  | Generalized linear mixed models (GLMM) were used to analyze primary outcome of Dizziness Handicap Inventory (DHI) scores over 3 months, adjusting for study arm, baseline score, time, interaction terms, age, and gender. |  |
| Additional Analysis |  | Exploratory subgroup analyses based on age and symptom duration; sensitivity analysis with multiple imputation and inverse probability weighting. |  |
| Missing Data Handling |  | Multiple imputation (m=40) was used for missing follow-up data, combined with inverse probability weighting in sensitivity analysis. |  |
| Statistical Software |  | All statistical analyses were conducted using R version 4.0.4. |  |
| Assignment Methods | Method to Assign Units to Study Conditions |  | Participants were assigned to treatment arms (ED-VeRT or usual care) at the discretion of the treating physician. |  |
| Unit of Assignment |  | Individual patient level. |  |
| Restrictions |  | No formal restrictions such as blocking or stratification were applied. |  |
| Bias Minimization Method |  | Baseline differences were adjusted for in models; the study design acknowledges limitations due to nonrandom assignment. |  |
| Other Methods | Methods to Account Variance |  | GLMM used with random participant effects; physician effects excluded due to lack of variation. |  |
| Recruitment Methods |  | Patients assessed for eligibility by research assistants during working hours and selected evenings/weekends. |  |
| Sampling Methods |  | Convenience sample based on ED visits for dizziness within the study period. |  |
| Quality Enhancing Methods |  | Use of validated outcome instruments (DHI, VAAI-9). |  |
| Data Collecting Methods |  | Structured REDCap surveys at 1 week, 1 month, 2 months, and 3 months post-visit. |  |
| Intervention Delivery Methods |  | In-person one-on-one delivery during ED visit. |  |
| Sampling Methods |  |  |  |
| Quality Enhancing Methods |  |  |  |
| Data Collecting Methods |  |  |  |
| Intervention Delivery Methods |  |  |  |

11.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Class | Attributes | Manual extraction | LLM extraction | TP, FP, FN |
| Study | Study Name |  |  |  |
| Authors |  |  |  |
| Publisher |  |  |  |
| PublishDate |  |  |  |
| Design |  |  |  |
| Objective |  |  |  |
| Hypothese |  |  |  |
| Interventions | Content |  |  |  |
| Exposure quantity |  |  |  |
| Duration |  |  |  |
| Activities to Increase Compliance or Adherence |  |  |  |
| Intervention Delivery | Unit of Delivery |  |  |  |
| Setting |  |  |  |
| Time Span |  |  |  |
| Intervention Deliverer |  |  |  |
| Analysis | Unit of Analysis |  |  |  |
| Recruitment | Setting |  |  |  |
| Location |  |  |  |
| Outcomes | Primary Outcome |  |  |  |
| Secondary Outcome |  |  |  |
| Validated Instruments |  |  |  |
| Binding | Accomplishment |  |  |  |
| Assignment |  |  |  |
| Participation criteria | Min Age |  |  |  |
| Max Age |  |  |  |
| Eligibility Criteria |  |  |  |
| Number of participants |  |  |  |
| Sample | Sample Size |  |  |  |
| Determination |  |  |  |
| Explanation Inherim Analyses and Stopping Rule |  |  |  |
| Statistical Methods | Primary Outcome Analysis |  |  |  |
| Additional Analysis |  |  |  |
| Missing Data Handling |  |  |  |
| Statistical Software |  |  |  |
| Assignment Methods | Method to Assign Units to Study Conditions |  |  |  |
| Unit of Assignment |  |  |  |
| Restrictions |  |  |  |
| Bias Minimization Method |  |  |  |
| Other Methods | Methods to Account Variance |  |  |  |
| Recruitment Methods |  |  |  |
| Sampling Methods |  |  |  |
| Quality Enhancing Methods |  |  |  |
| Data Collecting Methods |  |  |  |
| Intervention Delivery Methods |  |  |  |