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Evaluation of absenteeism, pain and disability in nurses with persistent low back pain following Cognitive Functional Therapy – a case-series pilot study with three years follow-up

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(1)   TITLE PAGE

Evaluation of absenteeism, pain and disability in nurses with persistent low back pain following Cognitive Functional Therapy – a case-series pilot study with three years follow-up

(2) ABSTRACT

Background: Persistent low back pain (PLBP) is a common and costly health problem

worldwide. Better strategies to manage it are required.

Objectives: To longitudinally evaluate absenteeism, pain and disability in nurses with PLBP

following a Cognitive Functional Therapy (CFT) intervention.

Design: Case-series pilot study.

Methods: Thirty-three eligible nurses with PLBP were recruited. During the baseline phase A

(no intervention) outcome measures were collected on two occasions six months apart (A1

and A2). During phase B, subjects participated in an individualised CFT intervention for 14

weeks. During phase C (no intervention) outcomes were measured immediately after the

intervention, as well as three, six, nine, 12 and 36 months after the intervention (secondary

outcomes only until 12 months). LBP-related work absenteeism, pain intensity (Numeric

Rating Scale) and disability (Oswestry Disability Index) were the primary outcomes.

Healthcare seeking, a range of psychological and lifestyle variables, and global perceived

effect were secondary outcomes.

Results: Days of absenteeism due to LBP were significantly reduced in the first and second

calendar year after the CFT intervention (p<0.05), but not the third and fourth. Disability **was**

significantly reduced **immediately after (-4.4; 95%CI [-6.5, -2.2]; p<0.001) and at three (-4.3;

95%CI [-6.6, -2.0]; p<0.001), nine (-6.0; 95%CI [-8.1, -3.9]; p<0.001) and 12 (-4.9; 95%CI [-

7.0, -2.8]; p<0.001) months** after the intervention. **Pain was significantly reduced

immediately after (-1.2; 95%CI [-1.7, -0.8]; p<0.001) and at three (-1.5; 95%CI [-2.0, -0.9];

p<0.001), nine (-1.1; 95%CI [-1.9, -0.3]; p=0.005) and 12 (-0.9; 95%CI [-1.5, -0.2]; p=0.007)

months after the intervention.** Total healthcare seeking (consults and **proportion** of

subjects) was significantly reduced after the intervention (p<0.001 and p<0.004). All

psychosocial variables, except for one, demonstrated significant improvements at all follow-

ups (p<0.02).

Conclusions: This case-series pilot study demonstrated significant reductions in LBP-related

absenteeism, pain intensity, disability, healthcare seeking and several psychological and

lifestyle behaviours until one year follow-up among nurses with PLBP following an

individualised CFT intervention. Further evaluating the efficacy of CFT in high quality

randomised clinical trials among nurses is recommended.

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1   ## (3)   Body of manuscript

2   ## INTRODUCTION

3   Persistent low back pain (PLBP) is a common and costly health problem worldwide.[1,2] Nurses

4   report higher rates of LBP than those employed in heavy industry.[3] The annual prevalence of

5   LBP in nurses is approximately 70%[4-8] and the lifetime prevalence ranges from 35% to

6   84%.[9,10] Recurrence rates of LBP in general and in nurses exceed 70%.[11,12] Based on

7   occupational medicine figures in Belgium, 12% of absenteeism lasting 28 days or more is

8   caused by LBP.[1] LBP-related absenteeism in nurses thus has an enormous impact on the

9   employee and employer. At an individual level; low personal income, limited opportunities

10   for promotion and career development, reduced work motivation and indirectly increased

11   chances of becoming unemployed are reported.[13,14] At the employer's level; costs of

12   treatment benefits and staff substitution, reduced productivity (presenteeism) which in turn

13   can have a negative impact on the economy in general are reported.[14] Therefore, LBP in

14   nurses can be considered a major health problem, and more effective strategies to manage

15   LBP in nurses are required.[1,15]

16   In recent decades, LBP has been conceptualized as a biopsychosocial disorder, where a range

17   of physical, psychological, social and lifestyle factors have been implicated.[2,16] Dealing

18   specifically with nurses, this same range of risk factors is potentially relevant. For example, it

19   has been proposed that nurses may be at risk of LBP due to their job involving some

20   bending, lifting and awkward static and dynamic working postures.[17,18] Other important risk

21   factors for nurses include job-related sleep deprivation[19,20] and shift work,[21] high stress and

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22   potentially low job satisfaction,[22,23] while nurses may also have reduced physical fitness and

23   strength,[24,25] and unhelpful beliefs about LBP.[16]

24   A range of interventions have been tested on reducing LBP in nurses. While these

25   interventions have shown some limited efficacy, no consistent evidence is presently

26   available to support their widespread application[26,27] and clinical guidelines are scarce.[28] A

27   recent systematic review concluded that there is no strong evidence for any intervention in

28   treating or preventing LBP in nurses.[15] A key reason identified was that most interventions

29   offered were unidimensional, and/or were not adequately tailored to the individual needs of

30   nurses with LBP.[26,29,30]

31   An individualised multidimensional Clinical Reasoning Framework (CRF) acknowledges that

32   for each individual there is a unique contribution of behaviours across different domains

33   (patho-anatomical, physical, neuro-physiological, psychological, social and lifestyle) that act

34   to maintain a vicious cycle of pain and disability. [31,32] This CRF has shown good reliability[33,34]

35   and has been described in detail elsewhere.[31,35,36]

36   Based on this CRF a targeted Cognitive Functional Therapy (CFT) intervention has been

37   suggested.[31,36] CFT is a novel individualised self-management approach that targets

38   unhelpful psychological, social, physical and lifestyle behaviours.[31,37,38] Clinical trials applying

39   CFT have shown encouraging outcomes.[39,40] For example, CFT has been tested in a

40   randomised controlled trial (RCT) with moderately disabled PLBP subjects, and

41   demonstrated superior outcomes on pain intensity, disability and absenteeism at both three

42   and twelve months follow-up compared to manual therapy and exercise.[39] Additionally, in a

43   case-series study, CFT significantly reduced pain intensity and disability at three, six and

44   twelve months follow-up among people with moderate to highly disabling PLBP.[40]

5

45 Furthermore, a recent clinical trial in Ireland demonstrated that individualised CFT reduced

46 disability, albeit not pain, in people with PLBP to a greater extent than a group-based

47 education and exercise programme.[41]

48 Despite these promising results, CFT has never been evaluated in a specific working

49 population of nurses with persistent and recurrent LBP. Performing an adequately powered

50 RCT would be premature, given the specific features of this population (working nurses with

51 persistent and recurrent LBP, but with lower levels of pain and disability).[39] Therefore, we

52 performed a pilot study aiming to longitudinally evaluate possible clinical changes in this

53 specific population following a CFT intervention. This is important before progressing to an

54 RCT, as case-series designs are advocated in the developmental stages of novel interventions

55 for persistent pain.[42-44] These designs allow interpretation of the changes that occur with

56 treatment and fine-tuning of the intervention before an RCT.

57 Therefore, as a precursor to future RCTs in nurses, the aim of this case-series pilot study with

58 long-term follow-up was to evaluate absenteeism, pain and disability in nurses with PLBP

59 following a CFT intervention.

60 **METHODS**

61 **Study design**

62 A case-series pilot study, consisting of three phases (A-B-C) was used (Figure 1). During

63 *phase A, s*elf-reported baseline primary and secondary outcome measures were collected

64 for all participants on two occasions six months apart (A1 and A2), during which no

65 intervention took place. During *phase B*, subjects participated in an individualised CFT

66 intervention for 14 weeks. Subjects were asked to cease every treatment for LBP while

67   undergoing the CFT intervention. At the end of the CFT intervention, participants were

68   expected and stimulated to continue their newly learned cognitive, physical and lifestyle

69   behaviours using the strategies developed during the intervention period and for the

70   duration of the follow-up period. If deemed necessary, subjects were allowed to engage

71   again in any usual care they received before the intervention. *Phase C* was the follow-up

72   period in which primary and secondary outcomes were measured immediately after the

73   intervention, and at three, six, nine months and one and three years follow-up (C1, C2, C3,

74   C4, C5, C6) (secondary outcomes only until C5). Ethical approval was obtained from the

75   Ethics Committee of KU Leuven, Belgium (ref. S54606 - ML8842). The study was registered

76   on ClinicalTrials.gov (ref: NCT01882686).

Subjects

78   Nurses (including nursing aides) were recruited from a residential care centre (Lille,

79   Belgium). All nurses were contacted by leaflet, email and personal letter and were invited to

80   participate. Only nurses with LBP were included and they were eligible if they met the

81   following inclusion criteria: constant or intermittent PLBP for more than three months,

82   including the four weeks prior to testing; a pain intensity on the Numerical Rating Scale

83   (NRS) of ≥ 1/10; an Oswestry Disability Index (ODI) score ≥ 2%; aged between 18-65 years;

84   independently mobile and capable of participating in a treatment programme incorporating

85   an exercise component; LBP primarily localised from T12 to the gluteal folds, and mainly

86   provoked with postures, movements and activities. Participants with additional pain regions

87   (e.g. thoracic, neck) were only included if LBP was the main problem. Participants were

88   excluded if they had: specific spinal pathology (e.g. specific LBP) based on relevant

89   investigations (such as malignancy, fracture, infection, spinal or foraminal stenosis,

90   spondylolisthesis, or inflammatory joint or bone disease), presence of red flags, previous

7

91   lumbar spinal surgery, were pregnant or less than six months postpartum, had a diagnosed

92   psychiatric disorder (e.g. depression), progressive neurological disease, serious cardiac or

93   other internal medical condition, infections or acute vascular catastrophes. 33 nurses

94   provided written informed consent prior to participation in accordance with the declaration

95   of Helsinki, and entered the study. Figure 1 illustrates the study design and number of

96   participating nurses through the various stages of the study.

97   **ADD FIGURE 1 ABOUT HERE**

Clinical assessment and intervention

99   After the first baseline measurement (A1), all participants with PLBP (n=33) underwent a

100   comprehensive one-to-one interview and physical examination by a specialist

101   musculoskeletal physiotherapist with three years of experience (WVH or NV). The clinical

102   assessment was based on the CRF and explored and identified relevant multidimensional

103   factors considered to be key drivers of their persistent LBP. Based on the patient clinical

104   assessment, clear individual goals for behaviour change were agreed upon.

105   The first CFT session was approximately 60 minutes and the eight individual follow-up

106   sessions were approximately 30 minutes in duration. The frequency and duration of the CFT

107   intervention varied in a pragmatic manner based on the progression of the participant. The

108   minimum duration was ten weeks. Initially the frequency of the sessions was once a week

109   gradually reducing to once every two weeks.

110   There were three main components to the CFT intervention (adapted from[35,36,40]); (1)

111   Making sense of pain: this helped the patient 'make sense' of their pain based on the

112   multidimensional factors identified within the clinical assessment, and which behaviours

8

113   may be reinforcing their vicious cycle of pain, disability and absenteeism. This aims to

114   dethreaten pain by reinforcing the structural integrity of the spine and through a cognitive

115   reconceptualization that pain does not equal tissue damage; (2) Exposure with 'control': this

116   consisted of *(2a) Normalisation of specific movements and pain control:* providing strategies

117   to normalise postural and movement behaviours that they nominated as painful, feared or

118   that they avoided (e.g. work-related activities like transferring or washing a patient, cleaning

119   bed, sitting…) and *(2b) Targeted functional integration:* integration of the 'new' postural,

120   movement and cognitive behaviours into each person's nominated pain-provocative

121   activities or tasks and directed at their valued functional goals; (3) Lifestyle change: this

122   promoted gradually increasing regular (3-5 days/week) physical activity, based on their

123   preference and presentation. If relevant, participants were given exercise, sleep and stress

124   management advice. This CFT intervention used a motivational approach and was

125   underpinned by a strong therapeutic alliance.[45,46] The CFT examination and intervention is

126   described in more detail elsewhere.[36]

Outcome measures

128   Participants provided a range of demographic information, including age, sex, height, body

129   mass and years of work at the residential care setting using the Dutch Musculoskeletal

130   Questionnaire (DMQ).[47]

Primary outcome measures

132   Work absenteeism due to LBP was objectively recorded by the administration section of the

133   workplace (the total number of days of absenteeism due to LBP, each calendar year per

134   subject). For every day of absenteeism subjects needed to have a certificate of absence from

135   the General Practitioner mentioning the reason for absenteeism. The total days of

136   absenteeism due to LBP and the total number of subjects having absenteeism were

137   calculated per calendar year, starting from the calendar year before the intervention until

138   the fourth calendar year after the CFT intervention. The intervention started between late

139   December and February, so the first calendar year after the intervention actually includes

140   the three month intervention period. The fourth calendar year includes the three years

141   follow-up of the other primary outcomes.

142   The NRS measured average LBP intensity during the past week. This is an 11-point scale

143   ranging from 0 (no pain) to 10 (worst imaginable pain) that has been demonstrated to be

144   valid, reliable and appropriate for use in clinical practice.[48,49] A 30% improvement from

145   baseline, has been identified as the minimally important change (MIC).[50]

146   The ODI was used to measure disability.[51,52] The reliability of the ODI is acceptable.[53] A 30%

147   improvement from baseline, has been identified as the MIC.[50]

Secondary outcome measures

149   The level of physical activity was evaluated using the Baecke scale for physical activity.[54]

150   Depression, anxiety and stress were measured by the Depression, Anxiety and Stress Scale

151   (DASS21).[55-57] Subjects' beliefs about LBP were measured using the Back Beliefs

152   Questionnaire (BBQ).[58,59] The Insomnia Severity Index (ISI) evaluated sleeping problems.[60,61]

153   The Pain Self-Efficacy Questionnaire (PSEQ) evaluated self-efficacy.[62] The Tampa Scale of

154   Kinesiophobia (TSK11) measured fear avoidance.[63,64] The Keele StarT Back Screening Tool

155   (SBST) was used to identify patients "at risk" for PLBP symptoms.[65,66]

156   The DMQ[47] evaluated healthcare seeking due to LBP during the last six months (total

157   number of consults and total number of subjects) ("How many times did you consult a

10

158   healthcare professional (General Practitioner and/or Physiotherapist and/or

159   Osteopath/Chiropractor) for your LBP in the last six months?").

160   Global Perceived Effect (GPE) evaluated, on a 7-point likert scale (1-7), the nurses' feelings

161   and satisfaction about the effect of the CFT and the evolution of their LBP ("To what extent

162   have you recovered from LBP since the beginning of the intervention?" and "how satisfied

163   are you with the CFT intervention you received?").

Treatment monitoring and fidelity

165   The two physiotherapists were trained to competency in the use of the CRF and the

166   application of the CFT intervention. This was based on knowledge (one 3 day course, two 2

167   day courses and six clinical workshops with a certified CFT educator (WD or POS) – a total of

168   104 hours of training) and clinical mentoring (skill acquisition) by ongoing follow-up and

169   case-by-case discussion with a principal certified CFT educator (WD).

170   To enhance treatment fidelity, a session-by-session report was written for every patient,

171   documenting the number of treatments, specific content of each treatment session, which

172   physical activity was advised and which home exercises were given. **Every session, the**

173   **patients were reminded to cease every other intervention for their LBP and to report any**

174   **interventions received.** The mean number of treatments was 8.8 (SD 1.3) over a mean

175   duration of 13.8 weeks (SD 1.25).

Statistical analysis

177   The reliability of two of the three primary outcome measures (NRS, ODI) were initially

178   assessed across the two baselines (Phase A) using the intra-class correlation coefficient (ICC,

179   two-way mixed). In the primary analysis, the mean of the two baseline measurements (A1,

11

180 A2) was used.[67] All follow-up measures were compared to this baseline (average of A1 and

181 A2) value. All outcome data were tested for normality of distribution (Shapiro-Wilk, $p<0.05$)

182 **and several measures were not normally distributed.**

183 **Mean changes of follow-up measures (C1-C6) versus baseline in primary outcomes of NRS**

184 **and ODI were analysed by constructing linear models estimated using generalized**

185 **estimation equations (GEE), with an exchangeable working correlation matrix. Thereby,**

186 **estimates of population averages were obtained along with confidence intervals**

187 **calculated using robust standard errors. To validate the GEE approach, a parallel analysis**

188 **for ODI and NRS using the non-parametric Friedman test was also conducted. The median**

189 **(interquartile range) change scores for ODI and NRS were also calculated. The number of**

190 **participants whose disability and pain remained at least 30% lower than baseline after the**

191 **intervention was also evaluated.**

192 **For the final primary outcome of LBP-related absenteeism, changes across the five**

193 **calendar years were analysed using the Friedman test. To analyse the change in the**

194 **proportion of subjects with LBP-related absenteeism following the CFT intervention, a**

195 **series of McNemar tests were used.**

196 **The psychological and lifestyle secondary outcomes (Baecke, DASS21, BBQ, ISI, PSEQ,**

197 **TSK11) were compared across the six-time intervals (Baseline, C1-5) using both a linear**

198 **model (GEE) and a parallel Friedman test. The median (interquartile range) change scores**

199 **were also calculated. Changes across the seven-time intervals (Baseline, C1-6) of the**

200 **secondary outcome healthcare seeking were analysed using the Friedman test. A series of**

201 **McNemar tests were used to analyse the change in the proportion of subjects seeking**

202 **healthcare following the CFT intervention.**

203 **Statistical significance for all outcome measures was set at p<0.05. The Friedman test was**

204 **followed by the post-hoc Wilcoxon Signed Ranks Tests to compare changes from baseline.**

205 **A Bonferroni-Holm correction was used to correct for multiple comparisons in the GEE**

206 **analyses as well as in the post-hoc Wilcoxon Signed Ranks Tests.[68] The level of adjustment**

207 **to alpha (p<0.05) was based on the amount of analysed comparisons and was six for ODI,**

208 **NRS and healthcare seeking (p<0.008), four for absenteeism (p<0.0125) and five for the**

209 **psychological and lifestyle variables (p<0.01).**

210 **Missing data was excluded pairwise in GEE (N=30 for C1, C2 and C5; N=28 at C3; N=29 at C4**

211 **and N=24 at C6) and a value was imputed for every missing value using the last**

212 **observation carried forward in the non-parametric analyses (Friedman and post-hoc**

213 **Wilcoxon Signed Ranks Tests). All statistical analyses were performed with IBM SPSS**

214 **Statistics, Version 25.0.**

215 ## RESULTS

216 The characteristics of the 30 nurses (all female) who completed the CFT intervention are

217 shown in Table 1. Three nurses were excluded before the start of the CFT intervention

218 (Figure 1). One additional subject became pregnant during the follow-up period. She

219 completed all the follow-up measures, except for C3 (6 months follow-up). She was not

220 excluded as her pregnancy was after she had already completed the intervention.

221 Based on the SBST at baseline, all subjects were considered "low risk" for persistent LBP

222 symptoms.[65] Based on ODI scores at baseline, 27 subjects (90%) had low disability (≤20%),

223 and three subjects (10%) had moderate disability (21%-40%).[69]

224 **ADD TABLE 1 ABOUT HERE**

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Reliability of baseline measures

226 The reliability of the ODI (ICC=.80, range=.59–.91) and NRS (ICC=.76, range=.49–.88) was

227 good. Baseline measures of the primary and secondary outcome measures (A1 versus A2)

228 were not significantly different from each other (all p>0.05).

Primary outcome measures

230 **Total days of** LBP-related absenteeism (of ten nurses, 33%) was significantly reduced after

231 the CFT intervention (χ^2=15.74, p=0.003), in the first (p**=0.005)** and second (p**=0.045**)

232 calendar year after the intervention. Changes in the third and fourth calendar year were not

233 significantly different from the calendar year before the intervention (Table 2). Specific data

234 on LBP-related absenteeism of each individual nurse with absenteeism is presented in Figure

235 2. **The proportion** of subjects **without** LBP-related absenteeism **was** significantly **reduced** in

236 the first **(χ^2=9.0, p=0.004), third (χ^2=6.4, p=0.021) and fourth (χ^2=6.4, p=0.021),** but not the

237 second, calendar year after the intervention (Table 2). However, as only ten nurses (33%)

238 experienced LBP-related absenteeism before the CFT intervention and 63% (105 days) was

239 due to the very high absenteeism of one nurse, interpretation of these data on absenteeism

240 needs caution. Nevertheless, even if the nurse with very high absenteeism was removed, the

241 rate of absenteeism at baseline remained higher than at any other period of the study (62

242 days at baseline compared to 0, 17, 15 and 28 days in respectively the 1st, 2nd, 3rd or 4th

243 calendar year after CFT) and reduced significantly in the 1st, but not the other, calendar years

244 (p=0.008) after the intervention. The **proportion of subjects without** absenteeism remained

245 **significantly reduced** at the third **(χ^2=5.44, p=0.039)** and fourth **(χ^2=5.44, p=0.039), but not**

246 **the second**, calendar year after the intervention.

247 **ADD TABLE 2 ABOUT HERE AND ADD FIGURE 2 ABOUT HERE**

14

248   Table 3 represents all data of disability and pain intensity at baseline and all follow-ups.

249   **Mean** disability was significantly reduced immediately (C1) after (**mean change, -4.4; 95%CI**

250   **[-6.5, -2.2]; p<0.001)** the CFT intervention, as well as three (C2) **(mean change, -4.3; 95%CI [-**

251   **6.6, -2.0]; p<0.001)**, nine (C4) **(mean change, -6.0; 95%CI [-8.1, -3.9]; p<0.001)** and 12

252   months (C5) **(mean change, -4.9; 95%CI [-7.0, -2.8]; p<0.001)** after the intervention.

253   However, at three years follow-up (C6) the reduction was no longer statistically significant

254   **(mean change, -1.9; 95%CI [-7.4, 3.6]; p=0.5)** (Table 3). **The parallel** analysis **(non-**

255   **parametric tests)** revealed the same **pattern**, except that the reduction**s** at C3 and C6 were

256   significant (p<0.02). **Thereby, both the linear models (using GEE) and the non-parametric**

257   **analysis validate each other. The observed mean changes for disability (estimated from**

258   **GEE) at C1, C2, C4 and C5 exceeded the MIC of a 30% reduction (3.39 points on ODI) from**

259   **baseline (Table 3). However, at an individual level, o**ne year after the intervention 70%

260   (21/30) of nurses remained improved beyond the MIC of 30%. Three years after the

261   intervention, this had reduced to 57% (17/30) of nurses.

262   **ADD TABLE 3 ABOUT HERE**

263   **Mean p**ain intensity was significantly reduced immediately (C1) **after (mean change, -1.2;**

264   **95%CI [-1.7, -0.8]; p<0.001)**, three (C2) **(mean change, -1.5; 95%CI [-2.0, -0.9]; p<0.001)**,

265   nine (C4) **(mean change, -1.1; 95%CI [-1.9, -0.3]; p=0.005)** and 12 (C5) **(mean change, -0.9;**

266   **95%CI [-1.5, -0.2]; p=0.007)** months after the intervention (Table 3). However, reductions in

267   pain intensity were no longer statistically significant at three years (C6) follow-up **(mean**

268   **change, -0.8; 95%CI [-1.7, 0.04]; p=0.06). The parallel** analysis **(non-parametric tests)**

269   revealed the same significant reductions, **validating the GEE analysis. The observed mean**

270   **changes of pain (estimated from GEE) at C1, C2, C4 and C5 exceeded the MIC of a 30%**

15

271 **reduction (0.78 on NRS) from baseline (Table 3). However, at an individual level, one** year

272 after the intervention 67% (20/30) of nurses and three years after the intervention 60%

273 (18/30) of nurses improved beyond the MIC of 30%.

Secondary outcome measures

275 Total healthcare seeking (consults) for LBP (by 20 nurses, 67%) was significantly reduced

276 after the CFT intervention (χ^2=48.61, p<0.001) for all follow-ups. The **proportion** of subjects

277 **no longer** seeking healthcare for LBP **was** also significant after the CFT intervention at all

278 follows (p<0.004) (Table 2).

279

280 Table 4 shows an overview of the psychosocial and lifestyle outcome measures. The Baecke

281 scale for physical activity was significantly increased (more physically active) at C1, C2 and C5

282 (p≤0.003). The BBQ was significantly increased (less negative beliefs about LBP) at all follow-

283 ups (p<0.001). The DASS21 total as well as the depression, anxiety and stress subscales of

284 the DASS21 were significantly reduced (less emotional distress) at all follow-ups (p≤0.02).

285 The ISI was significantly reduced (improved sleep) at all follow-ups (p≤0.003). The TSK11 was

286 significantly reduced (less pain-related fear) at all follow-ups (p≤0.02) and the PSEQ was

287 significantly increased (more self-efficacy) at all follow-ups (p≤0.01). **Parallel** analyses

288 revealed the same findings, except for Baecke at C1, for the psychological and lifestyle

289 outcome measures after the CFT intervention (Table 4).

290 Analysis of the GPE scales showed that one and three years after the CFT intervention, 70%

291 and 67% of nurses felt either completely or much improved and 23% and 20% of nurses felt

292 rather improved. Only 3% of nurses with PLBP felt no change three years after the CFT

16

293   intervention. One year after the CFT intervention, all subjects were absolutely (50%), very

294   (37%) or just (13%) satisfied with the CFT intervention they received.

295   **ADD TABLE 4 ABOUT HERE**

296   ## DISCUSSION

297   This case-series pilot study demonstrated significantly reduced LBP-related absenteeism in

298   nurses with PLBP following an individualised CFT intervention. This was sustained for up to

299   two, but not in the third and fourth, calendar years after the intervention. Pain intensity and

300   disability were significantly reduced until one year after the CFT intervention, but not at six

301   months and three years follow-up.

302   Comparing these reductions in LBP-related absenteeism with other studies is difficult due to

303   a small sample size. Further, few studies have assessed multidimensional interventions in

304   nurses and used absenteeism as a primary outcome measure. Linton et al. 1989 showed that

305   a multidimensional intervention in nurses (incorporating exercises like walking, swimming,

306   jogging, cycling, manual handling training in addition to behavioural therapy) significantly

307   reduced LBP intensity at six months follow-up but without changing the sick leave between

308   both groups.[70] Similarly, Svensson et al. 2011 reported a significantly (p<0.05) lower rate of

309   increase in sickness absence (+12 days (+/-20) vs. +18 (+/-34)) in nurses allocated to a

310   multidimensional prevention program (physical training, patient transfer technique

311   education and stress management with personal development) compared to a control group

312   (standard program in nursing assistant students) at 14 months but not at three years follow-

313   up.[71] In contrast, Roussel et al. 2015 concluded that a 12-week multidisciplinary prevention

314   program in caregiving hospital workers (intervention at hospital policy level, general health

315   (exercise and nutritional intervention), ergonomics and psychological intervention) was not

17

316 effective in preventing LBP incidence or avoiding work absenteeism due to LBP compared to

317 no intervention at six months follow-up.[72] Rasmussen et al. 2016 conducted a stepped

318 wedge cluster RCT in elderly care workers with PLBP, and reported that while a multi-faceted

319 workplace intervention (participatory ergonomics, physical training and cognitive

320 behavioural therapy) significantly improved physical work demands and fear avoidance

321 beliefs, it did not significantly decrease absenteeism due to LBP.[73]

322 Despite the lower pain and disability scores in the present pilot study, LBP-related

323 absenteeism significantly reduced in the two calendar years after the CFT intervention. Pain

324 and disability reduction do not seem sufficient to reduce absenteeism, especially when pain

325 and disability are rather low initially, as seen in the current pilot study. The non-linear nature

326 of the relationship between pain, disability and absenteeism is well documented. For

327 example, Sharma et al. 2016 found that LBP intensity was only weakly associated with lost

328 work days, leading them to suggest that managing how to deal with persistent pain and

329 remain active despite pain is more important to reduce lost work days.[74] To reduce LBP-

330 related absenteeism, an intervention has to be comprehensive enough to not only focus on

331 traditional work-related physical factors (e.g. ergonomic devices, manual handling training),

332 but also on the individual's psychological, movement and lifestyle factors,[26,29] as was done in

333 this individualized CFT intervention. Indeed, CFT aims to dethreaten pain through cognitive

334 reconceptualization (first component of CFT) and through promoting the concept that

335 engagement in movements and activities that load the spine is safe and beneficial for spine

336 health.[75] Additionally, even though the workplace where this pilot study took place provided

337 their personnel with ergonomic devices (e.g. transfer belts, lifts) and organizational support

338 (e.g. lift teams, back schooling), high rates of LBP prevalence and high LBP-related

339 absenteeism were observed. There appears to be a strong focus on these work-related

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340   physical factors in the literature,[3,76-78] even though more recent literature challenges the

341   current widespread use of no-lift policies and focus on so called 'correct lifting'

342   techniques.[15,27,79,80]

343   Careful interpretation of the absenteeism data is necessary, as only ten nurses (33%)

344   experienced LBP-related absenteeism before the CFT intervention and this data was

345   influenced by the very high absenteeism of one nurse. Nevertheless, even if the nurse with

346   very high absenteeism was removed, significant finding in days of- and **proportion** of

347   subjects with- LBP-related absenteeism were found.

348   Reducing absenteeism due to LBP, as evaluated in this pilot study, can have a large positive

349   impact for the individual, the employer and the society. Indeed, the reductions in days of

350   absenteeism in this study had important cost saving effects for the employer and the

351   employee (personal costs). The average cost saving for the employer was €150,801 per year

352   with a total saved cost in the four years after CFT of €603,204 (due to the decrease in

353   absenteeism and based on the cost of €1002 per individual per day of absenteeism[81]). Even

354   without the one nurse with very high absenteeism at baseline, the average cost saving for

355   the employer would be €47,094 per year with a total saved cost in the four years after CFT of

356   €188,376. While a full economic cost-effective evaluation was beyond the scope of this pilot

357   study, the literature supports the positive cost-saving impact of reducing absenteeism. For

358   example, Linton et al. 1993 showed that an early activation intervention significantly

359   reduced long-term absenteeism with greater economic impact compared to treatment as

360   usual.[82]

361   **The reductions for both disability and pain for many individual nurses exceeded the MIC,**

362   **as did the observed group mean changes at C1, C2, C4 and C5. However, magnitude of**

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363   **these changes was small, and the MIC value was usually within the confidence intervals at**

364   **follow-up. Therefore, caution is required when making conclusions regarding how clinically**

365   **meaningful these changes are at a group level.** Since pain and disability scores were low at

366   baseline, it is arguable that there was minimal room for improvement in these parameters.

367   However, despite the low levels of pain and disability, baseline absenteeism was meaningful,

368   suggesting that factors other than pain, such as pain beliefs, coping and self-efficacy may be

369   more important targets in order to reduce work absenteeism.

370   Our findings are in line with previous CFT intervention studies in other LBP populations. In

371   moderately disabled PLBP subjects, CFT significantly improved pain and disability at both

372   three and twelve months follow-up compared to manual therapy and exercise.[39] That

373   previous trial also demonstrated that the CFT group were three times less likely to take sick-

374   leave for their LBP at 12 months. Further, among people with moderate to highly disabling

375   PLBP,[40,41] in cyclists[83] and in rowers[84] with PLBP, CFT has been shown to significantly reduce

376   pain and disability. Together, this supports that CFT is a flexible integrated behavioural

377   approach for individualizing the management of PLBP that may be widely applicable in the

378   LBP population and across other painful musculoskeletal disorders.[36]

379   In line with the reduction in work absenteeism, there were also large significant reductions

380   in healthcare seeking (number of consults and subjects). This may indicate that the nurses

381   adopted a more active, self-managing coping style following the intervention. Indeed,

382   despite the increased LBP-related absenteeism in some nurses after the intervention,

383   healthcare seeking for LBP did not increase correspondingly.

384   While the precise underlying mechanism(s) for the CFT intervention are not clear, analysis of

385   the secondary outcomes revealed a significant change in a wide range of psychological and

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386 lifestyle factors after the CFT intervention. Beliefs about LBP (BBQ), stress, anxiety and

387 depression levels (DASS21), sleep (ISI), pain-related fear (TSK11) and self-efficacy (PSEQ)

388 significantly improved until one year follow-up. This is in line with other studies evaluating

389 the efficacy of CFT in subjects with LBP and finding changes in psychological and lifestyle

390 outcomes.[39,40] Other intervention studies targeting multiple dimensions associated with a

391 person's pain have shown encouraging outcome.[66,85] It would be interesting to explore

392 whether additional booster sessions would help maintain improvements, and manage

393 intermittent flare-ups, in the long-term.[36]

394 This case-series pilot study adds insight on the utility of a CFT intervention in a specific

395 nursing population. Based on these results, **future RCT's investigating** the CFT intervention

396 can be fine-tuned. **For example, considering that two-thirds (n=20) of eligible nurses**

397 **reported no absenteeism in the calendar year before the intervention, raising the bar for**

398 **eligibility (e.g. to at least one day of LBP-related absenteeism in the past year, pain**

399 **intensity >2 on the NRS and/or >12% on ODI) should be considered. Furthermore, adding**

400 **an activity tracker could objectively monitor physical activity,[86] sport and sleeping**

401 **patterns, and allow the treatment to be more individually fine-tuned on those aspects**

402 **with a view to long-term maintenance. Similarly, including a greater emphasis on**

403 **nutrition, stress- and flare-up management could reduce the number of post-treatment**

404 **flares reported.** Future research should evaluate more nursing-specific outcome measures

405 using more appropriate questionnaires in order to better determine recovery and treatment

406 response in **different** populations of working nurses with PLBP. The Patient Specific Function

407 Scale[87] could be a more appropriate primary outcome measure instead of the ODI for

408 evaluating disability. Additionally, qualitatively examining nurses' beliefs on why they did, or

409 did not, seek care or take time off work could be valuable.

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Limitations

The absence of a control group in this pilot study is a major limitation and does not allow

comparison with another intervention, such that the observed improvements could be

influenced by factors such as natural history, regression to the mean, and other non-specific

effects. Additionally, any conclusion about the specific effects of the different components

of the intervention is limited because the multidimensional nature of the intervention.

Future high quality RCT's with an appropriate control group that investigates matching

versus non-matching of interventions may help identify the effects of specific aspects of the

intervention. The performed analysis only evaluated outcome comparison between time

points. We did not control for confounding variables and effect modification. Future studies

with a larger sample size and a control group should include this. The magnitude of pain and

disability changes were low, so these results have to be interpreted with caution. The

outcome assessor was not blinded for the outcome measures, except for absenteeism.

However, these other outcome measures were self-reported and processed digitally. We

had no overall absenteeism data, limiting results to LBP-related absenteeism. Including this

data would be useful in future studies. We cannot be sure participants were not receiving

other interventions during the CFT intervention, because this was based on subjects'

subjective information. Medication use for LBP was not measured in this pilot study, which

could have influenced the results. Considering medication usage as a potential confounding

factor in future RCT's is recommended. Workplace ergonomic and organisational risk factors

were not specifically studied, but could also be included in future research.

22

Conclusion

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432   This case-series pilot study demonstrated significant reductions in LBP-related absenteeism,

433   pain intensity **and** disability **until one year follow-up among nurses with PLBP following an**

434   **individualised CFT intervention. Additionally,** healthcare seeking and several psychological

435   and lifestyle behaviours **demonstrated significant improvements** until one year follow-up. In

436   this specific occupational population of nurses where PLBP is a major health problem these

437   results are promising. Due to the absence of a control group, evaluating the efficacy of CFT in

438   high quality RCTs is warranted.

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(5) Tables

Table 1: Characteristics of the included nurses (all female) studied.

Baseline characteristics	Mean (SD) (N=30)
Age	44.7 (8.0)
Body mass (kg)	68.1 (8.5)
Height (cm)	167.6 (5.8)
BMI (kg/m^2)	24.2 (2.8)
Years of work	18.6 (8.7)
Hours work/week	30.2 (10.5)
LBP duration (years)	9.7 (6.8)

N: number, Kg: kilogram, cm: centimetres, BMI: Body Mass Index, SD: standard deviation, LBP: Low Back

Pain.

Table 2: LBP-related absenteeism and Healthcare seeking at baseline and follow-up

periods.

LBP-related absenteeism	Days	% reduction	N (%)	No longer absent / New absence (N)	McNemar (χ^2)
1y before CFT	167		10 (33.3)		
1st y after CFT	6*	96,4	1 (3.3)	9/0	9.0**
2nd y after CFT	17*	89,8	4 (13.3)	9/3	3.0
3rd y after CFT	15	91,0	2 (6.7)	9/1	6.4**
4th y after CFT	28	83,2	2 (6.7)	9/1	6.4**
HCseeking	Consults	% reduction	N (%)	No longer HCseeking / New HCseeking (N)	McNemar (χ^2)
Baseline	245		20 (66.7)		
C1	49*	80,0	8 (26.7)	12/0	12.0**
C2	50*	79,6	7 (23.3)	13/0	13.0**
C3	44*	82,0	9 (30)	11/0	11.0**
C4	37*	84,9	8 (26.7)	12/0	12.0**
C5	31*	87,3	9 (30)	12/1	9.3**
C6	31*	87,3	5 (16.7)	15/0	15.0**

LBP: Low Back Pain, HCseeking: HealthCare Seeking, Days: days of absenteeism due to LBP, Consults: amount of

consults with a healthcare provider (general practitioner, physiotherapist, chiropractor/osteopath), % reduction:

percentage of reduction in days of LBP-related absenteeism compared to the year before the intervention, **N**

(%): *amount of subjects having LBP-related absenteeism and/or seek healthcare* **with the percentage**

calculated based on the total group of nurses (N=30), No longer absent / New absence (N): numbers of

subjects who changed from having absenteeism before the CFT intervention to having no absenteeism in a

later year (and vice-versa), No longer HCseeking / New HCseeking (N): number of subjects who changed from

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seeking healthcare before the CFT intervention to not seeking healthcare in a later year (and vice-versa),

McNemar (χ^2): McNemar Chi-square statistics *analysing change in proportion of subjects with LBP-related*

absenteeism and/or HCseeking following the CFT intervention, for LBP-related absenteeism: '1y before CFT': is

the year before the start of the CFT intervention, '1ˢᵗ y after CFT': first calendar year after A2 (so it includes the

CFT intervention), '2ⁿᵈ y after CFT': second calendar year after the CFT intervention', '3ʳᵈ y after CFT': third

calendar year after the CFT intervention, '4ᵗʰ y after CFT': fourth calendar year after the CFT intervention, for

HCseeking: Baseline: baseline measurement, C1-6: follow-up measurements after the CFT intervention (C1:

immediately after the intervention, C2: 3 months after, C3: 6 months after, C4: 9 months after, C5: 12 months

after, C6: 3 years after), *: significantly different from baseline (Friedman and post-hoc Wilcoxon signed rank

test) (Bonferroni-Holm with 4 levels of adjustments to p<0.05 (0.0125, 0.0167, 0.025, 0.05), **: significantly

different from baseline (McNemar test) (p<0.02 for absenteeism and p<0.004 for HCseeking).*

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Table 3: ODI and NRS at baseline (average A1-A2) and follow-up periods (C1-6).

	Mean (SD)	GEE statistics comparing mean changes vs. Baseline			Median (IQR) scores for outcome		N (%) of subjects demonstrating MIC
		Estimate	95% Wald CI		Score	Change compared to baseline	
			lower	upper			
ODI							
Baseline	11.3 (7.7)				9.0 (9.3)		
C1	6.9 (8.3)	-4.4*	-6.5	-2.2	3.1 (8.3)**	4.0 (6.4)	18 (60)
C2	7.0 (8.5)	-4.3*	-6.6	-2.0	4.0 (8.5)**	4.6 (6.4)	21 (70)
C3	10.4 (11.4)	-1.1	-4.3	2.0	7.0 (11.3)**	3.0 (5.3)	13 (43)
C4	5.4 (6.0)	-6.0*	-8.1	-3.9	3.1 (6.0)**	5.0 (6.3)	21 (70)
C5	6.4 (8.5)	-4.9*	-7.0	-2.8	4.0 (8.5)**	5.0 (7.3)	21 (70)
C6	9.4 (15.9)	-1.9	-7.4	3.6	6.0 (14.4)**	3.0 (8.3)	17 (57)
NRS							
Baseline	2.6 (1.6)				2.0 (2.5)		
C1	1.3 (1.8)	-1.2*	-1.7	-0.8	1.0 (1.8)**	1.0 (1.1)	22 (73)
C2	1.1 (1.6)	-1.5*	-2.0	-0.9	1.0 (1.6)**	1.5 (1.5)	25 (83)
C3	2.1 (2.5)	-0.5	-1.1	0.2	1.0 (2.4)	1.0 (2.1)	20 (67)
C4	1.5 (2.0)	-1.1*	-1.9	-0.3	1.0 (2)**	1.5 (1.8)	23 (77)
C5	1.7 (2.0)	-0.9*	-1.5	-0.2	1.0 (2)**	1.0 (2.1)	20 (67)
C6	1.8 (2.2)	-0.8	-1.7	0.04	1.0 (2.1)	1.1 (2.6)	18 (60)

Mean (SD): observed mean and SD (Standard Deviation), GEE: Generalised Estimation Equation comparing mean changes of follow-ups (C1-C6) versus baseline (average A1-A2), *Estimate: mean change score from baseline – negative scores indicate improvement,* CI: Confidence interval, Med: Median, IQR: Interquartile Range, *Change compared to baseline: change score from baseline* (=Baseline score - C1, 2, 3, 4, 5 or C6 score) *– represented as Median (IQR) – positive change scores indicate improvement, **N (%) of subjects demonstrating MIC: number of subjects whose disability (ODI) and pain (NRS) remained at least 30% (Minimal Important Change) lower than baseline – percentage is calculated based on the total group of nurses (N=30),** MIC: Minimal Important Change, ODI: Oswestry Disability Index, NRS: Numerical Pain Rating Scale, Baseline: baseline measurement, C1-6: follow-up measurements after the CFT intervention (C1: immediately after the intervention, C2: 3 months after, C3: 6 months after, C4: 9 months after, C5: 12 months after, C6: 3 years after), note that with GEE analysis N=30 for C1, 2 and 5, N=28 at C3, N=29 at C4 and N=24 at C6, for **parallel** analysis **(non-parametric)** N=30 for all outcomes and missing values were analysed using the last observation carried forward method, *: Significant mean changes from baseline with GEE (Bonferroni-Holm **with 6 levels of adjustments to $p<0.05$ (0.008, 0.01, 0.0125, 0.0167, 0.025, 0.05)**), **: Significantly different from baseline with Wilcoxon signed rank test (Bonferroni-Holm, **with 6 levels of adjustments to $p<0.05$**).*

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Table 4: Secondary outcome measures at baseline (average A1-A2) and follow-up periods

(C1-5).

| | | GEE statistics comparing mean changes vs. Baseline | | | Median (IQR) scores for outcome | |
	Mean (SD)	Estimate	95% Wald CI lower	upper	Score	Change compared to baseline
Baecke						
Baseline	9.0 (1.4)				9.0 (2.5)	
C1	9.5 (1.1)	0.5*	0.2	0.8	9.6 (1.6)	-0.3 (1.5)
C2	9.7 (1.3)	0.6*	0.3	1.0	10.1 (2.1)**	-0.5 (1.1)
C3	9.3 (1.4)	0.3	-0.1	0.7	9.4 (2.3)	-0.2 (1.4)
C4	9.4 (1.2)	0.3	-0.1	0.7	9.5 (1.7)	-0.2 (1.4)
C5	9.6 (1.4)	0.5*	0.2	0.8	9.8 (2.4)**	-0.4 (1.3)
BBQ						
Baseline	30.7 (4.8)				31.0 (6.1)	
C1	34.5 (5.5)	3.8*	1.9	5.7	35.5 (9.3)**	-4.3 (9.5)
C2	36.4 (5.8)	5.7*	3.6	7.7	37.5 (7.5)**	-4.5 (8.3)
C3	35.4 (5.3)	5.0*	3.0	7.0	38.0 (9.3)**	-5.3 (9.1)
C4	35.6 (5.4)	5.0*	3.2	6.8	36.0 (8.0)**	-3.3 (6.0)
C5	35.2 (5.6)	4.5*	2.5	6.4	35.0 (8.5)**	-4.3 (8.4)
DASS21-Tot						
Baseline	15.7 (13.4)				13.5 (7.3)	
C1	9.0 (11.6)	-6.7*	-10.4	-3.0	5.0 (12.0)**	5.5 (11.0)
C2	6.5 (8.8)	-9.2*	-13.1	-5.2	4.0 (8.5)**	7.0 (8.8)
C3	7.5 (8.3)	-8.6*	-12.8	-4.4	3.0 (12.5)**	6.5 (14.0)
C4	10.0 (11.2)	-5.8*	-10.0	-1.7	6.0 (18.5)**	5.5 (11.0)
C5	7.0 (9.5)	-8.7*	-13.1	-4.3	2.0 (14.5)**	5.0 (15.8)
DASS21-DEPR						
Baseline	3.8 (4.6)				3.0 (5.5)	
C1	2.1 (4.0)	-1.7*	-3.0	-0.4	0.0 (2.0)**	1.0 (3.3)
C2	0.9 (2.3)	-2.9*	-4.3	-1.4	0.0 (2.0)**	1.5 (4.3)
C3	1.8 (3.0)	-2.1*	-3.4	-0.7	0.0 (2.5)**	1.0 (4.0)
C4	2.0 (3.2)	-1.8*	-3.3	-0.3	0.0 (4.0)**	1.0 (4.0)
C5	1.1 (2.6)	-2.7*	-4.2	-1.3	0.0 (0.5)**	1.0 (4.0)
DASS21-ANX						
Baseline	3.9 (4.0)				3.0 (5.0)	
C1	1.9 (2.9)	-2.0*	-3.3	-0.6	2.0 (2.0)**	1.0 (3.3)
C2	1.7 (3.0)	-2.2*	-3.7	-0.8	0.0 (2.0)**	2.0 (3.0)
C3	1.5 (2.0)	-2.5*	-3.8	-1.1	0.0 (2.0)**	2.0 (2.8)
C4	2.1 (3.5)	-1.9*	-3.1	-0.6	0.0 (2.0)**	1.5 (3.0)
C5	1.9 (3.0)	-2.0*	-3.3	-0.6	0.0 (2.5)**	1.0 (3.3)
DASS21-STRESS						
Baseline	8.0 (6.2)				7.5 (11.3)	
C1	5.0 (6.8)	-3.0*	-4.8	-1.2	3.0 (8.0)**	2.0 (5.3)
C2	3.9 (5.0)	-4.1*	-5.7	-2.4	2.0 (7.0)**	3.0 (6.0)
C3	4.2 (4.6)	-4.0*	-5.8	-2.2	1.0 (8.0)**	3.0 (6.3)
C4	5.9 (6.2)	-2.2*	-3.9	-0.4	3.0 (12.0)**	2.0 (4.3)
C5	4.0 (5.9)	-4.0*	-6.0	-2.0	0.0 (6.5)**	3.5 (7.3)
ISI						
Baseline	8.8 (5.4)				8.5 (8.8)	
C1	5.2 (4.6)	-3.6*	-4.8	-2.4	5.0 (7.0)**	3.0 (5.3)
C2	5.0 (4.9)	-3.9*	-5.3	-2.5	4.0 (8.5)**	3.0 (5.4)
C3	6.7 (6.1)	-2.4*	-4.0	-0.8	5.0 (9.3)**	2.5 (4.1)
C4	5.3 (4.6)	-3.7*	-5.4	-2.0	4.0 (7.0)**	3.0 (5.1)
C5	5.3 (4.6)	-3.5*	-5.1	-1.9	4.0 (8.0)**	2.0 (4.0)
TSK11						
Baseline	19.6 (4.7)				18.8 (6.6)	
C1	16.8 (5.1)	-2.8*	-4.1	-1.5	15.5 (5.3)**	2.8 (5.6)
C2	17.0 (5.0)	-2.6*	-3.9	-1.2	16.0 (7.0)**	2.3 (4.3)
C3	17.9 (5.0)	-2.1*	-3.4	-0.7	16.5 (6.3)**	2.3 (4.8)
C4	17.3 (5.0)	-2.4*	-3.6	-1.2	15.5 (7.3)**	2.3 (4.9)
C5	17.5 (5.6)	-2.1*	-3.8	-0.3	16.0 (8.5)**	1.3 (6.9)
PSEQ						
Baseline	52.0 (6.2)				52.0 (9.8)	
C1	56.7 (5.6)	4.7*	2.6	6.8	59.5 (4.3)**	-5.3 (6.8)
C2	56.6 (9.4)	4.7*	1.5	7.8	60.0 (3.0)**	-5.8 (9.3)
C3	55.4 (7.9)	3.6*	0.8	6.3	60.0 (6.8)**	-3.5 (7.5)
C4	57.4 (3.7)	5.5*	3.8	7.2	59.5 (4.3)**	-5.3 (7.3)
C5	57.0 (5.2)	5.1*	3.2	6.9	60.0 (3.8)**	-5.8 (8.5)

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Mean (SD): observed mean and SD (Standard Deviation), GEE: Generalised Estimation Equation comparing mean changes of follow-ups (C1-C5) from baseline (average A1-A2), , **Estimate**: mean change score from baseline – negative scores indicate improvements, except for Baecke, BBQ and PSEQ where positive scores indicate improvement, CI: Confidence interval, Med: Median, IQR: Interquartile Range, **Change compared to baseline: change score from baseline** (=Baseline score - C1, 2, 3, 4, 5 score) – represented as Median (IQR) – positive change scores indicate improvement, except for Baecke, BBQ and PSEQ where negative change score indicate improvement, Baseline: baseline measurement (average A1-A2), C1-5: follow-up measurements after the CFT intervention every 3 months (C1: immediately after the intervention, C2: 3 months after, C3: 6 months after, C4: 9 months after, C5: 12 months after), Baecke: Baecke scale for physical activity, BBQ: Back Beliefs Questionnaire, DASS21: Depression, Anxiety and Stress Scale (21-items), DEPR: Depression, ANX: Anxiety, ISI: Insomnia Severity Index, TSK11: Tampa Scale of Kinesiophobia (11-items), PSEQ: Patient Self-Efficacy Questionnaire, note that with GEE analysis N=30 for C1, 2 and 5, N=28 at C3, N=29 at C4 and N=24 at C6, for **parallel** analysis **(non-parametric)** N=30 for all outcomes and missing values were analysed using the last observation carried forward method, *: Significant mean change score with GEE (Bonferroni-Holm **with 5 levels of adjustments to p<0.05 (0.01, 0.0125, 0.0167, 0.025, 0.05)**, **: Significantly different from baseline with Wilcoxon signed rank test (Bonferroni-Holm **with 5 levels of adjustments to p<0.05**).

(6)   Figure legends

Figure 1: Study design and flowchart of participants.

Figure 2: Days of absenteeism due to LBP per subject with absenteeism in the year before

and the four calendar years after the CFT intervention.

Total days of absenteeism due to LBP were calculated per calendar year, **black and grey bars**

are subjects having absenteeism before and after the CFT intervention (N=3), grey-pattern

bars and light grey bars are subjects with absenteeism before but not after the CFT

intervention (N=7), black-pattern bars are subjects with no absenteeism before but with

flare-up after the CFT intervention (N=4), CFT: Cognitive Functional Therapy, '1y before

CFT': is the year before the start of the CFT intervention, '1st y after CFT': first calendar year

after A2 (so it includes the CFT intervention), '2nd y after CFT': second calendar year after the

CFT intervention', '3rd y after CFT': third calendar year after the CFT intervention, '4th y after

CFT': fourth calendar year after the CFT intervention, LBP: Low Back pain, S: Subject.

(7)   Figures

Figures are uploaded as separate files.

(8)   Video legends

NA

(9)   Appendixes

NA

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(1)   TITLE PAGE

Evaluation of absenteeism, pain and disability in nurses with persistent low

back pain following Cognitive Functional Therapy – a case-series pilot study

with three years follow-up

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(2) ABSTRACT

Background: Persistent low back pain (PLBP) is a common and costly health problem

worldwide. Better strategies to manage it are required.

Objectives: To longitudinally evaluate absenteeism, pain and disability in nurses with PLBP

following a Cognitive Functional Therapy (CFT) intervention.

Design: Case-series pilot study.

Methods: Thirty-three eligible nurses with PLBP were recruited. During the baseline phase A

(no intervention) outcome measures were collected on two occasions six months apart (A1

and A2). During phase B, subjects participated in an individualised CFT intervention for 14

weeks. During phase C (no intervention) outcomes were measured immediately after the

intervention, as well as three, six, nine, 12 and 36 months after the intervention (secondary

outcomes only until 12 months). LBP-related work absenteeism, pain intensity (Numeric

Rating Scale) and disability (Oswestry Disability Index) were the primary outcomes.

Healthcare seeking, a range of psychological and lifestyle variables, and global perceived

effect were secondary outcomes.

Results: Days of absenteeism due to LBP were significantly reduced in the first and second

calendar year after the CFT intervention (p<0.05), but not the third and fourth. Disability **was**

significantly reduced **immediately after (-4.4; 95%CI [-6.5, -2.2]; p<0.001) and at three (-4.3;**

95%CI [-6.6, -2.0]; p<0.001), nine (-6.0; 95%CI [-8.1, -3.9]; p<0.001) and 12 (-4.9; 95%CI [-

7.0, -2.8]; p<0.001) months after the intervention. **Pain was significantly reduced**

immediately after (-1.2; 95%CI [-1.7, -0.8]; p<0.001) and at three (-1.5; 95%CI [-2.0, -0.9];

p<0.001), nine (-1.1; 95%CI [-1.9, -0.3]; p=0.005) and 12 (-0.9; 95%CI [-1.5, -0.2]; p=0.007)

months after the intervention. Total healthcare seeking (consults and **proportion** of

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3   subjects) was significantly reduced after the intervention (p<0.001 and p<0.004). All
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5   psychosocial variables, except for one, demonstrated significant improvements at all follow-
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7   ups (p<0.02).
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10   *Conclusions:* This case-series pilot study demonstrated significant reductions in LBP-related
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12   absenteeism, pain intensity, disability, healthcare seeking and several psychological and
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14   lifestyle behaviours until one year follow-up among nurses with PLBP following an
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16   individualised CFT intervention. Further evaluating the efficacy of CFT in high quality
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18   randomised clinical trials among nurses is recommended.
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1   **(3)   Body of manuscript**

2   **INTRODUCTION**

3   Persistent low back pain (PLBP) is a common and costly health problem worldwide.[1,2] Nurses

4   report higher rates of LBP than those employed in heavy industry.[3] The annual prevalence of

5   LBP in nurses is approximately 70%[4-8] and the lifetime prevalence ranges from 35% to

6   84%.[9,10] Recurrence rates of LBP in general and in nurses exceed 70%.[11,12] Based on

7   occupational medicine figures in Belgium, 12% of absenteeism lasting 28 days or more is

8   caused by LBP.[1] LBP-related absenteeism in nurses thus has an enormous impact on the

9   employee and employer. At an individual level; low personal income, limited opportunities

10   for promotion and career development, reduced work motivation and indirectly increased

11   chances of becoming unemployed are reported.[13,14] At the employer's level; costs of

12   treatment benefits and staff substitution, reduced productivity (presenteeism) which in turn

13   can have a negative impact on the economy in general are reported.[14] Therefore, LBP in

14   nurses can be considered a major health problem, and more effective strategies to manage

15   LBP in nurses are required.[1,15]

16   In recent decades, LBP has been conceptualized as a biopsychosocial disorder, where a range

17   of physical, psychological, social and lifestyle factors have been implicated.[2,16] Dealing

18   specifically with nurses, this same range of risk factors is potentially relevant. For example, it

19   has been proposed that nurses may be at risk of LBP due to their job involving some

20   bending, lifting and awkward static and dynamic working postures.[17,18] Other important risk

21   factors for nurses include job-related sleep deprivation[19,20] and shift work,[21] high stress and

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22 potentially low job satisfaction,[22,23] while nurses may also have reduced physical fitness and

23 strength,[24,25] and unhelpful beliefs about LBP.[16]

24 A range of interventions have been tested on reducing LBP in nurses. While these

25 interventions have shown some limited efficacy, no consistent evidence is presently

26 available to support their widespread application[26,27] and clinical guidelines are scarce.[28] A

27 recent systematic review concluded that there is no strong evidence for any intervention in

28 treating or preventing LBP in nurses.[15] A key reason identified was that most interventions

29 offered were unidimensional, and/or were not adequately tailored to the individual needs of

30 nurses with LBP.[26,29,30]

31 An individualised multidimensional Clinical Reasoning Framework (CRF) acknowledges that

32 for each individual there is a unique contribution of behaviours across different domains

33 (patho-anatomical, physical, neuro-physiological, psychological, social and lifestyle) that act

34 to maintain a vicious cycle of pain and disability. [31,32] This CRF has shown good reliability[33,34]

35 and has been described in detail elsewhere.[31,35,36]

36 Based on this CRF a targeted Cognitive Functional Therapy (CFT) intervention has been

37 suggested.[31,36] CFT is a novel individualised self-management approach that targets

38 unhelpful psychological, social, physical and lifestyle behaviours.[31,37,38] Clinical trials applying

39 CFT have shown encouraging outcomes.[39,40] For example, CFT has been tested in a

40 randomised controlled trial (RCT) with moderately disabled PLBP subjects, and

41 demonstrated superior outcomes on pain intensity, disability and absenteeism at both three

42 and twelve months follow-up compared to manual therapy and exercise.[39] Additionally, in a

43 case-series study, CFT significantly reduced pain intensity and disability at three, six and

44 twelve months follow-up among people with moderate to highly disabling PLBP.[40]

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45   Furthermore, a recent clinical trial in Ireland demonstrated that individualised CFT reduced

46   disability, albeit not pain, in people with PLBP to a greater extent than a group-based

47   education and exercise programme.[41]

48   Despite these promising results, CFT has never been evaluated in a specific working

49   population of nurses with persistent and recurrent LBP. Performing an adequately powered

50   RCT would be premature, given the specific features of this population (working nurses with

51   persistent and recurrent LBP, but with lower levels of pain and disability).[39] Therefore, we

52   performed a pilot study aiming to longitudinally evaluate possible clinical changes in this

53   specific population following a CFT intervention. This is important before progressing to an

54   RCT, as case-series designs are advocated in the developmental stages of novel interventions

55   for persistent pain.[42-44] These designs allow interpretation of the changes that occur with

56   treatment and fine-tuning of the intervention before an RCT.

57   Therefore, as a precursor to future RCTs in nurses, the aim of this case-series pilot study with

58   long-term follow-up was to evaluate absenteeism, pain and disability in nurses with PLBP

59   following a CFT intervention.

60   **METHODS**

61   **Study design**

62   A case-series pilot study, consisting of three phases (A-B-C) was used (Figure 1). During

63   *phase A, s*elf-reported baseline primary and secondary outcome measures were collected

64   for all participants on two occasions six months apart (A1 and A2), during which no

65   intervention took place. During *phase B*, subjects participated in an individualised CFT

66   intervention for 14 weeks. Subjects were asked to cease every treatment for LBP while

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3   67   undergoing the CFT intervention. At the end of the CFT intervention, participants were
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5   68   expected and stimulated to continue their newly learned cognitive, physical and lifestyle
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7   69   behaviours using the strategies developed during the intervention period and for the
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10   70   duration of the follow-up period. If deemed necessary, subjects were allowed to engage
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12   71   again in any usual care they received before the intervention. *Phase C* was the follow-up
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15   72   period in which primary and secondary outcomes were measured immediately after the
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17   73   intervention, and at three, six, nine months and one and three years follow-up (C1, C2, C3,
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20   74   C4, C5, C6) (secondary outcomes only until C5). Ethical approval was obtained from the
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22   75   Ethics Committee of KU Leuven, Belgium (ref. S54606 - ML8842). The study was registered
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24   76   on ClinicalTrials.gov (ref: NCT01882686).
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28   77   **Subjects**
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31   78   Nurses (including nursing aides) were recruited from a residential care centre (Lille,
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33   79   Belgium). All nurses were contacted by leaflet, email and personal letter and were invited to
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35
36   80   participate. Only nurses with LBP were included and they were eligible if they met the
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38   81   following inclusion criteria: constant or intermittent PLBP for more than three months,
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41   82   including the four weeks prior to testing; a pain intensity on the Numerical Rating Scale
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43   83   (NRS) of ≥ 1/10; an Oswestry Disability Index (ODI) score ≥ 2%; aged between 18-65 years;
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45
46   84   independently mobile and capable of participating in a treatment programme incorporating
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48   85   an exercise component; LBP primarily localised from T12 to the gluteal folds, and mainly
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50   86   provoked with postures, movements and activities. Participants with additional pain regions
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53   87   (e.g. thoracic, neck) were only included if LBP was the main problem. Participants were
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55   88   excluded if they had: specific spinal pathology (e.g. specific LBP) based on relevant
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58   89   investigations (such as malignancy, fracture, infection, spinal or foraminal stenosis,
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60   90   spondylolisthesis, or inflammatory joint or bone disease), presence of red flags, previous

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91   lumbar spinal surgery, were pregnant or less than six months postpartum, had a diagnosed

92   psychiatric disorder (e.g. depression), progressive neurological disease, serious cardiac or

93   other internal medical condition, infections or acute vascular catastrophes. 33 nurses

94   provided written informed consent prior to participation in accordance with the declaration

95   of Helsinki, and entered the study. Figure 1 illustrates the study design and number of

96   participating nurses through the various stages of the study.

97   **ADD FIGURE 1 ABOUT HERE**

98   ## Clinical assessment and intervention

99   After the first baseline measurement (A1), all participants with PLBP (n=33) underwent a

100 comprehensive one-to-one interview and physical examination by a specialist

101 musculoskeletal physiotherapist with three years of experience (WVH or NV). The clinical

102 assessment was based on the CRF and explored and identified relevant multidimensional

103 factors considered to be key drivers of their persistent LBP. Based on the patient clinical

104 assessment, clear individual goals for behaviour change were agreed upon.

105 The first CFT session was approximately 60 minutes and the eight individual follow-up

106 sessions were approximately 30 minutes in duration. The frequency and duration of the CFT

107 intervention varied in a pragmatic manner based on the progression of the participant. The

108 minimum duration was ten weeks. Initially the frequency of the sessions was once a week

109 gradually reducing to once every two weeks.

110 There were three main components to the CFT intervention (adapted from[35,36,40]); (1)

111 Making sense of pain: this helped the patient 'make sense' of their pain based on the

112 multidimensional factors identified within the clinical assessment, and which behaviours

113   may be reinforcing their vicious cycle of pain, disability and absenteeism. This aims to

114   dethreaten pain by reinforcing the structural integrity of the spine and through a cognitive

115   reconceptualization that pain does not equal tissue damage; (2) Exposure with 'control': this

116   consisted of *(2a) Normalisation of specific movements and pain control:* providing strategies

117   to normalise postural and movement behaviours that they nominated as painful, feared or

118   that they avoided (e.g. work-related activities like transferring or washing a patient, cleaning

119   bed, sitting…) and *(2b) Targeted functional integration:* integration of the 'new' postural,

120   movement and cognitive behaviours into each person's nominated pain-provocative

121   activities or tasks and directed at their valued functional goals; (3) Lifestyle change: this

122   promoted gradually increasing regular (3-5 days/week) physical activity, based on their

123   preference and presentation. If relevant, participants were given exercise, sleep and stress

124   management advice. This CFT intervention used a motivational approach and was

125   underpinned by a strong therapeutic alliance.[45,46] The CFT examination and intervention is

126   described in more detail elsewhere.[36]

Outcome measures

128   Participants provided a range of demographic information, including age, sex, height, body

129   mass and years of work at the residential care setting using the Dutch Musculoskeletal

130   Questionnaire (DMQ).[47]

Primary outcome measures

132   Work absenteeism due to LBP was objectively recorded by the administration section of the

133   workplace (the total number of days of absenteeism due to LBP, each calendar year per

134   subject). For every day of absenteeism subjects needed to have a certificate of absence from

135   the General Practitioner mentioning the reason for absenteeism. The total days of

9

136   absenteeism due to LBP and the total number of subjects having absenteeism were

137   calculated per calendar year, starting from the calendar year before the intervention until

138   the fourth calendar year after the CFT intervention. The intervention started between late

139   December and February, so the first calendar year after the intervention actually includes

140   the three month intervention period. The fourth calendar year includes the three years

141   follow-up of the other primary outcomes.

142   The NRS measured average LBP intensity during the past week. This is an 11-point scale

143   ranging from 0 (no pain) to 10 (worst imaginable pain) that has been demonstrated to be

144   valid, reliable and appropriate for use in clinical practice.[48,49] A 30% improvement from

145   baseline, has been identified as the minimally important change (MIC).[50]

146   The ODI was used to measure disability.[51,52] The reliability of the ODI is acceptable.[53] A 30%

147   improvement from baseline, has been identified as the MIC.[50]

Secondary outcome measures

149   The level of physical activity was evaluated using the Baecke scale for physical activity.[54]

150   Depression, anxiety and stress were measured by the Depression, Anxiety and Stress Scale

151   (DASS21).[55-57] Subjects' beliefs about LBP were measured using the Back Beliefs

152   Questionnaire (BBQ).[58,59] The Insomnia Severity Index (ISI) evaluated sleeping problems.[60,61]

153   The Pain Self-Efficacy Questionnaire (PSEQ) evaluated self-efficacy.[62] The Tampa Scale of

154   Kinesiophobia (TSK11) measured fear avoidance.[63,64] The Keele StarT Back Screening Tool

155   (SBST) was used to identify patients "at risk" for PLBP symptoms.[65,66]

156   The DMQ[47] evaluated healthcare seeking due to LBP during the last six months (total

157   number of consults and total number of subjects) ("How many times did you consult a

10

158   healthcare professional (General Practitioner and/or Physiotherapist and/or

159   Osteopath/Chiropractor) for your LBP in the last six months?").

160   Global Perceived Effect (GPE) evaluated, on a 7-point likert scale (1-7), the nurses' feelings

161   and satisfaction about the effect of the CFT and the evolution of their LBP ("To what extent

162   have you recovered from LBP since the beginning of the intervention?" and "how satisfied

163   are you with the CFT intervention you received?").

Treatment monitoring and fidelity

165   The two physiotherapists were trained to competency in the use of the CRF and the

166   application of the CFT intervention. This was based on knowledge (one 3 day course, two 2

167   day courses and six clinical workshops with a certified CFT educator (WD or POS) – a total of

168   104 hours of training) and clinical mentoring (skill acquisition) by ongoing follow-up and

169   case-by-case discussion with a principal certified CFT educator (WD).

170   To enhance treatment fidelity, a session-by-session report was written for every patient,

171   documenting the number of treatments, specific content of each treatment session, which

172   physical activity was advised and which home exercises were given. **Every session, the**

173   **patients were reminded to cease every other intervention for their LBP and to report any**

174   **interventions received.** The mean number of treatments was 8.8 (SD 1.3) over a mean

175   duration of 13.8 weeks (SD 1.25).

Statistical analysis

177   The reliability of two of the three primary outcome measures (NRS, ODI) were initially

178   assessed across the two baselines (Phase A) using the intra-class correlation coefficient (ICC,

179   two-way mixed). In the primary analysis, the mean of the two baseline measurements (A1,

11

180   A2) was used.[67] All follow-up measures were compared to this baseline (average of A1 and

181   A2) value. All outcome data were tested for normality of distribution (Shapiro-Wilk, $p < 0.05$)

182   **and several measures were not normally distributed.**

183   **Mean changes of follow-up measures (C1-C6) versus baseline in primary outcomes of NRS**

184   **and ODI were analysed by constructing linear models estimated using generalized**

185   **estimation equations (GEE), with an exchangeable working correlation matrix. Thereby,**

186   **estimates of population averages were obtained along with confidence intervals**

187   **calculated using robust standard errors. To validate the GEE approach, a parallel analysis**

188   **for ODI and NRS using the non-parametric Friedman test was also conducted. The median**

189   **(interquartile range) change scores for ODI and NRS were also calculated. The number of**

190   **participants whose disability and pain remained at least 30% lower than baseline after the**

191   **intervention was also evaluated.**

192   **For the final primary outcome of LBP-related absenteeism, changes across the five**

193   **calendar years were analysed using the Friedman test. To analyse the change in the**

194   **proportion of subjects with LBP-related absenteeism following the CFT intervention, a**

195   **series of McNemar tests were used.**

196   **The psychological and lifestyle secondary outcomes (Baecke, DASS21, BBQ, ISI, PSEQ,**

197   **TSK11) were compared across the six-time intervals (Baseline, C1-5) using both a linear**

198   **model (GEE) and a parallel Friedman test. The median (interquartile range) change scores**

199   **were also calculated. Changes across the seven-time intervals (Baseline, C1-6) of the**

200   **secondary outcome healthcare seeking were analysed using the Friedman test. A series of**

201   **McNemar tests were used to analyse the change in the proportion of subjects seeking**

202   **healthcare following the CFT intervention.**

12

203 **Statistical significance for all outcome measures was set at p<0.05. The Friedman test was**

204 **followed by the post-hoc Wilcoxon Signed Ranks Tests to compare changes from baseline.**

205 **A Bonferroni-Holm correction was used to correct for multiple comparisons in the GEE**

206 **analyses as well as in the post-hoc Wilcoxon Signed Ranks Tests.[68] The level of adjustment**

207 **to alpha (p<0.05) was based on the amount of analysed comparisons and was six for ODI,**

208 **NRS and healthcare seeking (p<0.008), four for absenteeism (p<0.0125) and five for the**

209 **psychological and lifestyle variables (p<0.01).**

210 **Missing data was excluded pairwise in GEE (N=30 for C1, C2 and C5; N=28 at C3; N=29 at C4**

211 **and N=24 at C6) and a value was imputed for every missing value using the last**

212 **observation carried forward in the non-parametric analyses (Friedman and post-hoc**

213 **Wilcoxon Signed Ranks Tests). All statistical analyses were performed with IBM SPSS**

214 **Statistics, Version 25.0.**

215 ## RESULTS

216 The characteristics of the 30 nurses (all female) who completed the CFT intervention are

217 shown in Table 1. Three nurses were excluded before the start of the CFT intervention

218 (Figure 1). One additional subject became pregnant during the follow-up period. She

219 completed all the follow-up measures, except for C3 (6 months follow-up). She was not

220 excluded as her pregnancy was after she had already completed the intervention.

221 Based on the SBST at baseline, all subjects were considered "low risk" for persistent LBP

222 symptoms.[65] Based on ODI scores at baseline, 27 subjects (90%) had low disability (≤20%),

223 and three subjects (10%) had moderate disability (21%-40%).[69]

224 **ADD TABLE 1 ABOUT HERE**

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Reliability of baseline measures

226 The reliability of the ODI (ICC=.80, range=.59–.91) and NRS (ICC=.76, range=.49–.88) was

227 good. Baseline measures of the primary and secondary outcome measures (A1 versus A2)

228 were not significantly different from each other (all p>0.05).

Primary outcome measures

230 **Total days of** LBP-related absenteeism (of ten nurses, 33%) was significantly reduced after

231 the CFT intervention (χ^2=15.74, p=0.003), in the first (p**=0.005)** and second (p**=0.045**)

232 calendar year after the intervention. Changes in the third and fourth calendar year were not

233 significantly different from the calendar year before the intervention (Table 2). Specific data

234 on LBP-related absenteeism of each individual nurse with absenteeism is presented in Figure

235 2. **The proportion** of subjects **without** LBP-related absenteeism **was** significantly **reduced** in

236 the first **(χ^2=9.0, p=0.004), third (χ^2=6.4, p=0.021) and fourth (χ^2=6.4, p=0.021),** but not the

237 second, calendar year after the intervention (Table 2). However, as only ten nurses (33%)

238 experienced LBP-related absenteeism before the CFT intervention and 63% (105 days) was

239 due to the very high absenteeism of one nurse, interpretation of these data on absenteeism

240 needs caution. Nevertheless, even if the nurse with very high absenteeism was removed, the

241 rate of absenteeism at baseline remained higher than at any other period of the study (62

242 days at baseline compared to 0, 17, 15 and 28 days in respectively the 1st, 2nd, 3rd or 4th

243 calendar year after CFT) and reduced significantly in the 1st, but not the other, calendar years

244 (p=0.008) after the intervention. The **proportion of subjects without** absenteeism remained

245 **significantly reduced** at the third **(χ^2=5.44, p=0.039)** and fourth **(χ^2=5.44, p=0.039), but not**

246 **the second**, calendar year after the intervention.

247 **ADD TABLE 2 ABOUT HERE AND ADD FIGURE 2 ABOUT HERE**

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248   Table 3 represents all data of disability and pain intensity at baseline and all follow-ups.

249   **Mean** disability was significantly reduced immediately (C1) after (**mean change, -4.4; 95%CI**

250   **[-6.5, -2.2]; p<0.001)** the CFT intervention, as well as three (C2) **(mean change, -4.3; 95%CI [-**

251   **6.6, -2.0]; p<0.001)**, nine (C4) **(mean change, -6.0; 95%CI [-8.1, -3.9]; p<0.001)** and 12

252   months (C5) **(mean change, -4.9; 95%CI [-7.0, -2.8]; p<0.001)** after the intervention.

253   However, at three years follow-up (C6) the reduction was no longer statistically significant

254   **(mean change, -1.9; 95%CI [-7.4, 3.6]; p=0.5)** (Table 3). **The parallel** analysis **(non-**

255   **parametric tests)** revealed the same **pattern**, except that the reduction**s** at C3 and C6 were

256   significant (p<0.02). **Thereby, both the linear models (using GEE) and the non-parametric**

257   **analysis validate each other. The observed mean changes for disability (estimated from**

258   **GEE) at C1, C2, C4 and C5 exceeded the MIC of a 30% reduction (3.39 points on ODI) from**

259   **baseline (Table 3). However, at an individual level, o**ne year after the intervention 70%

260   (21/30) of nurses remained improved beyond the MIC of 30%. Three years after the

261   intervention, this had reduced to 57% (17/30) of nurses.

262   **ADD TABLE 3 ABOUT HERE**

263   **Mean p**ain intensity was significantly reduced immediately (C1) **after (mean change, -1.2;**

264   **95%CI [-1.7, -0.8]; p<0.001)**, three (C2) **(mean change, -1.5; 95%CI [-2.0, -0.9]; p<0.001)**,

265   nine (C4) **(mean change, -1.1; 95%CI [-1.9, -0.3]; p=0.005)** and 12 (C5) **(mean change, -0.9;**

266   **95%CI [-1.5, -0.2]; p=0.007)** months after the intervention (Table 3). However, reductions in

267   pain intensity were no longer statistically significant at three years (C6) follow-up **(mean**

268   **change, -0.8; 95%CI [-1.7, 0.04]; p=0.06). The parallel** analysis **(non-parametric tests)**

269   revealed the same significant reductions, **validating the GEE analysis. The observed mean**

270   **changes of pain (estimated from GEE) at C1, C2, C4 and C5 exceeded the MIC of a 30%**

271 **reduction (0.78 on NRS) from baseline (Table 3). However, at an individual level, one** year

272 after the intervention 67% (20/30) of nurses and three years after the intervention 60%

273 (18/30) of nurses improved beyond the MIC of 30%.

Secondary outcome measures

275 Total healthcare seeking (consults) for LBP (by 20 nurses, 67%) was significantly reduced

276 after the CFT intervention (χ^2=48.61, p<0.001) for all follow-ups. The **proportion** of subjects

277 **no longer** seeking healthcare for LBP **was** also significant after the CFT intervention at all

278 follows (p<0.004) (Table 2).

279 Table 4 shows an overview of the psychosocial and lifestyle outcome measures. The Baecke

280 scale for physical activity was significantly increased (more physically active) at C1, C2 and C5

281 (p≤0.003). The BBQ was significantly increased (less negative beliefs about LBP) at all follow-

282 ups (p<0.001). The DASS21 total as well as the depression, anxiety and stress subscales of

283 the DASS21 were significantly reduced (less emotional distress) at all follow-ups (p≤0.02).

284 The ISI was significantly reduced (improved sleep) at all follow-ups (p≤0.003). The TSK11 was

285 significantly reduced (less pain-related fear) at all follow-ups (p≤0.02) and the PSEQ was

286 significantly increased (more self-efficacy) at all follow-ups (p≤0.01). **Parallel** analyses

287 revealed the same findings, except for Baecke at C1, for the psychological and lifestyle

288 outcome measures after the CFT intervention (Table 4).

289 Analysis of the GPE scales showed that one and three years after the CFT intervention, 70%

290 and 67% of nurses felt either completely or much improved and 23% and 20% of nurses felt

291 rather improved. Only 3% of nurses with PLBP felt no change three years after the CFT

292 intervention. One year after the CFT intervention, all subjects were absolutely (50%), very

293 (37%) or just (13%) satisfied with the CFT intervention they received.

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294   **ADD TABLE 4 ABOUT HERE**

295   ## DISCUSSION

296   This case-series pilot study demonstrated significantly reduced LBP-related absenteeism in

297   nurses with PLBP following an individualised CFT intervention. This was sustained for up to

298   two, but not in the third and fourth, calendar years after the intervention. Pain intensity and

299   disability were significantly reduced until one year after the CFT intervention, but not at six

300   months and three years follow-up.

301   Comparing these reductions in LBP-related absenteeism with other studies is difficult due to

302   a small sample size. Further, few studies have assessed multidimensional interventions in

303   nurses and used absenteeism as a primary outcome measure. Linton et al. 1989 showed that

304   a multidimensional intervention in nurses (incorporating exercises like walking, swimming,

305   jogging, cycling, manual handling training in addition to behavioural therapy) significantly

306   reduced LBP intensity at six months follow-up but without changing the sick leave between

307   both groups.[70] Similarly, Svensson et al. 2011 reported a significantly (p<0.05) lower rate of

308   increase in sickness absence (+12 days (+/-20) vs. +18 (+/-34)) in nurses allocated to a

309   multidimensional prevention program (physical training, patient transfer technique

310   education and stress management with personal development) compared to a control group

311   (standard program in nursing assistant students) at 14 months but not at three years follow-

312   up.[71] In contrast, Roussel et al. 2015 concluded that a 12-week multidisciplinary prevention

313   program in caregiving hospital workers (intervention at hospital policy level, general health

314   (exercise and nutritional intervention), ergonomics and psychological intervention) was not

315   effective in preventing LBP incidence or avoiding work absenteeism due to LBP compared to

316   no intervention at six months follow-up.[72] Rasmussen et al. 2016 conducted a stepped

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317   wedge cluster RCT in elderly care workers with PLBP, and reported that while a multi-faceted

318   workplace intervention (participatory ergonomics, physical training and cognitive

319   behavioural therapy) significantly improved physical work demands and fear avoidance

320   beliefs, it did not significantly decrease absenteeism due to LBP.[73]

321   Despite the lower pain and disability scores in the present pilot study, LBP-related

322   absenteeism significantly reduced in the two calendar years after the CFT intervention. Pain

323   and disability reduction do not seem sufficient to reduce absenteeism, especially when pain

324   and disability are rather low initially, as seen in the current pilot study. The non-linear nature

325   of the relationship between pain, disability and absenteeism is well documented. For

326   example, Sharma et al. 2016 found that LBP intensity was only weakly associated with lost

327   work days, leading them to suggest that managing how to deal with persistent pain and

328   remain active despite pain is more important to reduce lost work days.[74] To reduce LBP-

329   related absenteeism, an intervention has to be comprehensive enough to not only focus on

330   traditional work-related physical factors (e.g. ergonomic devices, manual handling training),

331   but also on the individual's psychological, movement and lifestyle factors,[26,29] as was done in

332   this individualized CFT intervention. Indeed, CFT aims to dethreaten pain through cognitive

333   reconceptualization (first component of CFT) and through promoting the concept that

334   engagement in movements and activities that load the spine is safe and beneficial for spine

335   health.[75] Additionally, even though the workplace where this pilot study took place provided

336   their personnel with ergonomic devices (e.g. transfer belts, lifts) and organizational support

337   (e.g. lift teams, back schooling), high rates of LBP prevalence and high LBP-related

338   absenteeism were observed. There appears to be a strong focus on these work-related

339   physical factors in the literature,[3,76-78] even though more recent literature challenges the

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340   current widespread use of no-lift policies and focus on so called 'correct lifting'

341   techniques.[15,27,79,80]

342   Careful interpretation of the absenteeism data is necessary, as only ten nurses (33%)

343   experienced LBP-related absenteeism before the CFT intervention and this data was

344   influenced by the very high absenteeism of one nurse. Nevertheless, even if the nurse with

345   very high absenteeism was removed, significant finding in days of- and **proportion** of

346   subjects with- LBP-related absenteeism were found.

347   Reducing absenteeism due to LBP, as evaluated in this pilot study, can have a large positive

348   impact for the individual, the employer and the society. Indeed, the reductions in days of

349   absenteeism in this study had important cost saving effects for the employer and the

350   employee (personal costs). The average cost saving for the employer was €150,801 per year

351   with a total saved cost in the four years after CFT of €603,204 (due to the decrease in

352   absenteeism and based on the cost of €1002 per individual per day of absenteeism[81]). Even

353   without the one nurse with very high absenteeism at baseline, the average cost saving for

354   the employer would be €47,094 per year with a total saved cost in the four years after CFT of

355   €188,376. While a full economic cost-effective evaluation was beyond the scope of this pilot

356   study, the literature supports the positive cost-saving impact of reducing absenteeism. For

357   example, Linton et al. 1993 showed that an early activation intervention significantly

358   reduced long-term absenteeism with greater economic impact compared to treatment as

359   usual.[82]

360   **The reductions for both disability and pain for many individual nurses exceeded the MIC,**

361   **as did the observed group mean changes at C1, C2, C4 and C5. However, magnitude of**

362   **these changes was small, and the MIC value was usually within the confidence intervals at**

19

363 **follow-up. Therefore, caution is required when making conclusions regarding how clinically**

364 **meaningful these changes are at a group level.** Since pain and disability scores were low at

365 baseline, it is arguable that there was minimal room for improvement in these parameters.

366 However, despite the low levels of pain and disability, baseline absenteeism was meaningful,

367 suggesting that factors other than pain, such as pain beliefs, coping and self-efficacy may be

368 more important targets in order to reduce work absenteeism.

369 Our findings are in line with previous CFT intervention studies in other LBP populations. In

370 moderately disabled PLBP subjects, CFT significantly improved pain and disability at both

371 three and twelve months follow-up compared to manual therapy and exercise.[39] That

372 previous trial also demonstrated that the CFT group were three times less likely to take sick-

373 leave for their LBP at 12 months. Further, among people with moderate to highly disabling

374 PLBP,[40,41] in cyclists[83] and in rowers[84] with PLBP, CFT has been shown to significantly reduce

375 pain and disability. Together, this supports that CFT is a flexible integrated behavioural

376 approach for individualizing the management of PLBP that may be widely applicable in the

377 LBP population and across other painful musculoskeletal disorders.[36]

378 In line with the reduction in work absenteeism, there were also large significant reductions

379 in healthcare seeking (number of consults and subjects). This may indicate that the nurses

380 adopted a more active, self-managing coping style following the intervention. Indeed,

381 despite the increased LBP-related absenteeism in some nurses after the intervention,

382 healthcare seeking for LBP did not increase correspondingly.

383 While the precise underlying mechanism(s) for the CFT intervention are not clear, analysis of

384 the secondary outcomes revealed a significant change in a wide range of psychological and

385 lifestyle factors after the CFT intervention. Beliefs about LBP (BBQ), stress, anxiety and

20

386   depression levels (DASS21), sleep (ISI), pain-related fear (TSK11) and self-efficacy (PSEQ)

387   significantly improved until one year follow-up. This is in line with other studies evaluating

388   the efficacy of CFT in subjects with LBP and finding changes in psychological and lifestyle

389   outcomes.[39,40] Other intervention studies targeting multiple dimensions associated with a

390   person's pain have shown encouraging outcome.[66,85] It would be interesting to explore

391   whether additional booster sessions would help maintain improvements, and manage

392   intermittent flare-ups, in the long-term.[36]

393   This case-series pilot study adds insight on the utility of a CFT intervention in a specific

394   nursing population. Based on these results, **future RCT's investigating** the CFT intervention

395   can be fine-tuned. **For example, considering that two-thirds (n=20) of eligible nurses**

396   **reported no absenteeism in the calendar year before the intervention, raising the bar for**

397   **eligibility (e.g. to at least one day of LBP-related absenteeism in the past year, pain**

398   **intensity >2 on the NRS and/or >12% on ODI) should be considered. Furthermore, adding**

399   **an activity tracker could objectively monitor physical activity,[86] sport and sleeping**

400   **patterns, and allow the treatment to be more individually fine-tuned on those aspects**

401   **with a view to long-term maintenance. Similarly, including a greater emphasis on**

402   **nutrition, stress- and flare-up management could reduce the number of post-treatment**

403   **flares reported.** Future research should evaluate more nursing-specific outcome measures

404   using more appropriate questionnaires in order to better determine recovery and treatment

405   response in **different** populations of working nurses with PLBP. The Patient Specific Function

406   Scale[87] could be a more appropriate primary outcome measure instead of the ODI for

407   evaluating disability. Additionally, qualitatively examining nurses' beliefs on why they did, or

408   did not, seek care or take time off work could be valuable.

21

Limitations

The absence of a control group in this pilot study is a major limitation and does not allow

comparison with another intervention, such that the observed improvements could be

influenced by factors such as natural history, regression to the mean, and other non-specific

effects. Additionally, any conclusion about the specific effects of the different components

of the intervention is limited because the multidimensional nature of the intervention.

Future high quality RCT's with an appropriate control group that investigates matching

versus non-matching of interventions may help identify the effects of specific aspects of the

intervention. The performed analysis only evaluated outcome comparison between time

points. We did not control for confounding variables and effect modification. Future studies

with a larger sample size and a control group should include this. The magnitude of pain and

disability changes were low, so these results have to be interpreted with caution. The

outcome assessor was not blinded for the outcome measures, except for absenteeism.

However, these other outcome measures were self-reported and processed digitally. We

had no overall absenteeism data, limiting results to LBP-related absenteeism. Including this

data would be useful in future studies. We cannot be sure participants were not receiving

other interventions during the CFT intervention, because this was based on subjects'

subjective information. Medication use for LBP was not measured in this pilot study, which

could have influenced the results. Considering medication usage as a potential confounding

factor in future RCT's is recommended. Workplace ergonomic and organisational risk factors

were not specifically studied, but could also be included in future research.

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Conclusion

430   This case-series pilot study demonstrated significant reductions in LBP-related absenteeism,

431   pain intensity **and** disability **until one year follow-up among nurses with PLBP following an**

432   **individualised CFT intervention. Additionally,** healthcare seeking and several psychological

433   and lifestyle behaviours **demonstrated significant improvements** until one year follow-up. In

434   this specific occupational population of nurses where PLBP is a major health problem these

435   results are promising. Due to the absence of a control group, evaluating the efficacy of CFT in

436   high quality RCTs is warranted.

(4)   ACKNOWLEDGEMENTS

Disclosures

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(6)   Tables

Table 1: Characteristics of the included nurses (all female) studied.

Baseline characteristics	Mean (SD) (N=30)
Age	44.7 (8.0)
Body mass (kg)	68.1 (8.5)
Height (cm)	167.6 (5.8)
BMI (kg/m²)	24.2 (2.8)
Years of work	18.6 (8.7)
Hours work/week	30.2 (10.5)
LBP duration (years)	9.7 (6.8)

N: number, Kg: kilogram, cm: centimetres, BMI: Body Mass Index, SD: standard deviation, LBP: Low Back Pain.

Table 2: LBP-related absenteeism and Healthcare seeking at baseline and follow-up periods.

LBP-related absenteeism	Days	% reduction	N (%)	No longer absent / New absence (N)	McNemar (χ^2)
1y before CFT	167		10 (33.3)		
1st y after CFT	6*	96,4	1 (3.3)	9/0	9.0**
2nd y after CFT	17*	89,8	4 (13.3)	9/3	3.0
3rd y after CFT	15	91,0	2 (6.7)	9/1	6.4**
4th y after CFT	28	83,2	2 (6.7)	9/1	6.4**
HCseeking	**Consults**	**% reduction**	**N (%)**	**No longer HCseeking / New HCseeking (N)**	**McNemar (χ^2)**
Baseline	245		20 (66.7)		
C1	49*	80,0	8 (26.7)	12/0	12.0**
C2	50*	79,6	7 (23.3)	13/0	13.0**
C3	44*	82,0	9 (30)	11/0	11.0**
C4	37*	84,9	8 (26.7)	12/0	12.0**
C5	31*	87,3	9 (30)	12/1	9.3**
C6	31*	87,3	5 (16.7)	15/0	15.0**

LBP: Low Back Pain, HCseeking: HealthCare Seeking, Days: days of absenteeism due to LBP, Consults: amount of consults with a healthcare provider (general practitioner, physiotherapist, chiropractor/osteopath), % reduction: percentage of reduction in days of LBP-related absenteeism compared to the year before the intervention, **N (%)**: *amount of subjects having LBP-related absenteeism and/or seek healthcare* **with the percentage calculated based on the total group of nurses (N=30), No longer absent / New absence (N): numbers of subjects who changed from having absenteeism before the CFT intervention to having no absenteeism in a later year (and vice-versa), No longer HCseeking / New HCseeking (N): number of subjects who changed from**

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seeking healthcare before the CFT intervention to not seeking healthcare in a later year (and vice-versa),

McNemar (χ^2): McNemar Chi-square *statistics* **analysing change in proportion of subjects with LBP-related**

absenteeism and/or HCseeking following the CFT intervention, *for LBP-related absenteeism: '1y before CFT': is*

the year before the start of the CFT intervention, '1st y after CFT': first calendar year after A2 (so it includes the

CFT intervention), '2nd y after CFT': second calendar year after the CFT intervention', '3rd y after CFT': third

calendar year after the CFT intervention, '4th y after CFT': fourth calendar year after the CFT intervention, for

HCseeking: Baseline: baseline measurement, C1-6: follow-up measurements after the CFT intervention (C1:

immediately after the intervention, C2: 3 months after, C3: 6 months after, C4: 9 months after, C5: 12 months

after, C6: 3 years after), ***: significantly different from baseline (Friedman and post-hoc Wilcoxon signed rank**

test) (Bonferroni-Holm with 4 levels of adjustments to p<0.05 (0.0125, 0.0167, 0.025, 0.05), **: significantly

different from baseline (McNemar test) (p<0.02 for absenteeism and p<0.004 for HCseeking).

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Table 3: ODI and NRS at baseline (average A1-A2) and follow-up periods (C1-6).

| | Mean (SD) | GEE statistics comparing mean changes vs. Baseline | | | Median (IQR) scores for outcome | | N (%) of subjects demonstrating MIC |
| | | Estimate | 95% Wald CI | | Score | Change compared to baseline | |
			lower	upper			
ODI							
Baseline	11.3 (7.7)				9.0 (9.3)		
C1	6.9 (8.3)	-4.4*	-6.5	-2.2	3.1 (8.3)**	4.0 (6.4)	18 (60)
C2	7.0 (8.5)	-4.3*	-6.6	-2.0	4.0 (8.5)**	4.6 (6.4)	21 (70)
C3	10.4 (11.4)	-1.1	-4.3	2.0	7.0 (11.3)**	3.0 (5.3)	13 (43)
C4	5.4 (6.0)	-6.0*	-8.1	-3.9	3.1 (6.0)**	5.0 (6.3)	21 (70)
C5	6.4 (8.5)	-4.9*	-7.0	-2.8	4.0 (8.5)**	5.0 (7.3)	21 (70)
C6	9.4 (15.9)	-1.9	-7.4	3.6	6.0 (14.4)**	3.0 (8.3)	17 (57)
NRS							
Baseline	2.6 (1.6)				2.0 (2.5)		
C1	1.3 (1.8)	-1.2*	-1.7	-0.8	1.0 (1.8)**	1.0 (1.1)	22 (73)
C2	1.1 (1.6)	-1.5*	-2.0	-0.9	1.0 (1.6)**	1.5 (1.5)	25 (83)
C3	2.1 (2.5)	-0.5	-1.1	0.2	1.0 (2.4)	1.0 (2.1)	20 (67)
C4	1.5 (2.0)	-1.1*	-1.9	-0.3	1.0 (2)**	1.5 (1.8)	23 (77)
C5	1.7 (2.0)	-0.9*	-1.5	-0.2	1.0 (2)**	1.0 (2.1)	20 (67)
C6	1.8 (2.2)	-0.8	-1.7	0.04	1.0 (2.1)	1.1 (2.6)	18 (60)

Mean (SD): observed mean and SD (Standard Deviation), GEE: Generalised Estimation Equation comparing mean changes of follow-ups (C1-C6) versus baseline (average A1-A2), **Estimate:** *mean change score from baseline – negative scores indicate improvement,* CI: Confidence interval, Med: Median, IQR: Interquartile Range, **Change compared to baseline:** *change score from baseline* (=Baseline score - C1, 2, 3, 4, 5 or C6 score) *– represented as Median (IQR) – positive change scores indicate improvement,* **N (%) of subjects demonstrating MIC: number of subjects whose disability (ODI) and pain (NRS) remained at least 30% (Minimal Important Change) lower than baseline – percentage is calculated based on the total group of nurses (N=30),** *MIC: Minimal Important Change, ODI: Oswestry Disability Index, NRS: Numerical Pain Rating Scale, Baseline: baseline measurement, C1-6: follow-up measurements after the CFT intervention (C1: immediately after the intervention, C2: 3 months after, C3: 6 months after, C4: 9 months after, C5: 12 months after, C6: 3 years after), note that with GEE analysis N=30 for C1, 2 and 5, N=28 at C3, N=29 at C4 and N=24 at C6, for* **parallel** *analysis* **(non-parametric)** *N=30 for all outcomes and missing values were analysed using the last observation carried forward method, *: Significant mean changes from baseline with GEE (Bonferroni-Holm* **with 6 levels of adjustments to p<0.05 (0.008, 0.01, 0.0125, 0.0167, 0.025, 0.05)**, **: Significantly different from baseline with Wilcoxon signed rank test (Bonferroni-Holm*, **with 6 levels of adjustments to p<0.05**).

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Table 4: Secondary outcome measures at baseline (average A1-A2) and follow-up periods

(C1-5).

| | | GEE statistics comparing mean changes vs. Baseline | | | Median (IQR) scores for outcome | |
	Mean (SD)	Estimate	95% Wald CI lower	upper	Score	Change compared to baseline
Baecke						
Baseline	9.0 (1.4)				9.0 (2.5)	
C1	9.5 (1.1)	0.5*	0.2	0.8	9.6 (1.6)	-0.3 (1.5)
C2	9.7 (1.3)	0.6*	0.3	1.0	10.1 (2.1)**	-0.5 (1.1)
C3	9.3 (1.4)	0.3	-0.1	0.7	9.4 (2.3)	-0.2 (1.4)
C4	9.4 (1.2)	0.3	-0.1	0.7	9.5 (1.7)	-0.2 (1.4)
C5	9.6 (1.4)	0.5*	0.2	0.8	9.8 (2.4)**	-0.4 (1.3)
BBQ						
Baseline	30.7 (4.8)				31.0 (6.1)	
C1	34.5 (5.5)	3.8*	1.9	5.7	35.5 (9.3)**	-4.3 (9.5)
C2	36.4 (5.8)	5.7*	3.6	7.7	37.5 (7.5)**	-4.5 (8.3)
C3	35.4 (5.3)	5.0*	3.0	7.0	38.0 (9.3)**	-5.3 (9.1)
C4	35.6 (5.4)	5.0*	3.2	6.8	36.0 (8.0)**	-3.3 (6.0)
C5	35.2 (5.6)	4.5*	2.5	6.4	35.0 (8.5)**	-4.3 (8.4)
DASS21-Tot						
Baseline	15.7 (13.4)				13.5 (7.3)	
C1	9.0 (11.6)	-6.7*	-10.4	-3.0	5.0 (12.0)**	5.5 (11.0)
C2	6.5 (8.8)	-9.2*	-13.1	-5.2	4.0 (8.5)**	7.0 (8.8)
C3	7.5 (8.3)	-8.6*	-12.8	-4.4	3.0 (12.5)**	6.5 (14.0)
C4	10.0 (11.2)	-5.8*	-10.0	-1.7	6.0 (18.5)**	5.5 (11.0)
C5	7.0 (9.5)	-8.7*	-13.1	-4.3	2.0 (14.5)**	5.0 (15.8)
DASS21-DEPR						
Baseline	3.8 (4.6)				3.0 (5.5)	
C1	2.1 (4.0)	-1.7*	-3.0	-0.4	0.0 (2.0)**	1.0 (3.3)
C2	0.9 (2.3)	-2.9*	-4.3	-1.4	0.0 (2.0)**	1.5 (4.3)
C3	1.8 (3.0)	-2.1*	-3.4	-0.7	0.0 (2.5)**	1.0 (4.0)
C4	2.0 (3.2)	-1.8*	-3.3	-0.3	0.0 (4.0)**	1.0 (4.0)
C5	1.1 (2.6)	-2.7*	-4.2	-1.3	0.0 (0.5)**	1.0 (4.0)
DASS21-ANX						
Baseline	3.9 (4.0)				3.0 (5.0)	
C1	1.9 (2.9)	-2.0*	-3.3	-0.6	2.0 (2.0)**	1.0 (3.3)
C2	1.7 (3.0)	-2.2*	-3.7	-0.8	0.0 (2.0)**	2.0 (3.0)
C3	1.5 (2.0)	-2.5*	-3.8	-1.1	0.0 (2.0)**	2.0 (2.8)
C4	2.1 (3.5)	-1.9*	-3.1	-0.6	0.0 (2.0)**	1.5 (3.0)
C5	1.9 (3.0)	-2.0*	-3.3	-0.6	0.0 (2.5)**	1.0 (3.3)
DASS21-STRESS						
Baseline	8.0 (6.2)				7.5 (11.3)	
C1	5.0 (6.8)	-3.0*	-4.8	-1.2	3.0 (8.0)**	2.0 (5.3)
C2	3.9 (5.0)	-4.1*	-5.7	-2.4	2.0 (7.0)**	3.0 (6.0)
C3	4.2 (4.6)	-4.0*	-5.8	-2.2	1.0 (8.0)**	3.0 (6.3)
C4	5.9 (6.2)	-2.2*	-3.9	-0.4	3.0 (12.0)**	2.0 (4.3)
C5	4.0 (5.9)	-4.0*	-6.0	-2.0	0.0 (6.5)**	3.5 (7.3)
ISI						
Baseline	8.8 (5.4)				8.5 (8.8)	
C1	5.2 (4.6)	-3.6*	-4.8	-2.4	5.0 (7.0)**	3.0 (5.3)
C2	5.0 (4.9)	-3.9*	-5.3	-2.5	4.0 (8.5)**	3.0 (5.4)
C3	6.7 (6.1)	-2.4*	-4.0	-0.8	5.0 (9.3)**	2.5 (4.1)
C4	5.3 (4.6)	-3.7*	-5.4	-2.0	4.0 (7.0)**	3.0 (5.1)
C5	5.3 (4.6)	-3.5*	-5.1	-1.9	4.0 (8.0)**	2.0 (4.0)
TSK11						
Baseline	19.6 (4.7)				18.8 (6.6)	
C1	16.8 (5.1)	-2.8*	-4.1	-1.5	15.5 (5.3)**	2.8 (5.6)
C2	17.0 (5.0)	-2.6*	-3.9	-1.2	16.0 (7.0)**	2.3 (4.3)
C3	17.9 (5.0)	-2.1*	-3.4	-0.7	16.5 (6.3)**	2.3 (4.8)
C4	17.3 (5.0)	-2.4*	-3.6	-1.2	15.5 (7.3)**	2.3 (4.9)
C5	17.5 (5.6)	-2.1*	-3.8	-0.3	16.0 (8.5)**	1.3 (6.9)
PSEQ						
Baseline	52.0 (6.2)				52.0 (9.8)	
C1	56.7 (5.6)	4.7*	2.6	6.8	59.5 (4.3)**	-5.3 (6.8)
C2	56.6 (9.4)	4.7*	1.5	7.8	60.0 (3.0)**	-5.8 (9.3)
C3	55.4 (7.9)	3.6*	0.8	6.3	60.0 (6.8)**	-3.5 (7.5)
C4	57.4 (3.7)	5.5*	3.8	7.2	59.5 (4.3)**	-5.3 (7.3)
C5	57.0 (5.2)	5.1*	3.2	6.9	60.0 (3.8)**	-5.8 (8.5)

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Mean (SD): observed mean and SD (Standard Deviation), *GEE: Generalised Estimation Equation comparing mean changes of follow-ups (C1-C5) from baseline (average A1-A2), ,* **Estimate***: mean change score from baseline – negative scores indicate improvements, except for Baecke, BBQ and PSEQ where positive scores indicate improvement, CI: Confidence interval, Med: Median, IQR: Interquartile Range,* **Change compared to baseline: change score from baseline** *(=Baseline score - C1, 2, 3, 4, 5 score) – represented as Median (IQR) – positive change scores indicate improvement, except for Baecke, BBQ and PSEQ where negative change score indicate improvement, Baseline: baseline measurement (average A1-A2), C1-5: follow-up measurements after the CFT intervention every 3 months (C1: immediately after the intervention, C2: 3 months after, C3: 6 months after, C4: 9 months after, C5: 12 months after), Baecke: Baecke scale for physical activity, BBQ: Back Beliefs Questionnaire, DASS21: Depression, Anxiety and Stress Scale (21-items), DEPR: Depression, ANX: Anxiety, ISI: Insomnia Severity Index, TSK11: Tampa Scale of Kinesiophobia (11-items), PSEQ: Patient Self-Efficacy Questionnaire, note that with GEE analysis N=30 for C1, 2 and 5, N=28 at C3, N=29 at C4 and N=24 at C6, for* **parallel** *analysis* **(non-parametric)** *N=30 for all outcomes and missing values were analysed using the last observation carried forward method, *: Significant mean change score with GEE (Bonferroni-Holm* **with 5 levels of adjustments to p<0.05 (0.01, 0.0125, 0.0167, 0.025, 0.05)***), **: Significantly different from baseline with Wilcoxon signed rank test (Bonferroni-Holm* **with 5 levels of adjustments to p<0.05***).*

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(7) Figure legends

Figure 1: Study design and flowchart of participants.

Figure 2: Days of absenteeism due to LBP per subject with absenteeism in the year before

and the four calendar years after the CFT intervention.

Total days of absenteeism due to LBP were calculated per calendar year, **black and grey bars**

are subjects having absenteeism before and after the CFT intervention (N=3), grey-pattern

bars and light grey bars are subjects with absenteeism before but not after the CFT

intervention (N=7), black-pattern bars are subjects with no absenteeism before but with

flare-up after the CFT intervention (N=4), CFT: Cognitive Functional Therapy, '1y before

CFT': is the year before the start of the CFT intervention, '1st y after CFT': first calendar year

after A2 (so it includes the CFT intervention), '2nd y after CFT': second calendar year after the

CFT intervention', '3rd y after CFT': third calendar year after the CFT intervention, '4th y after

CFT': fourth calendar year after the CFT intervention, LBP: Low Back pain, S: Subject.

(8) Figures
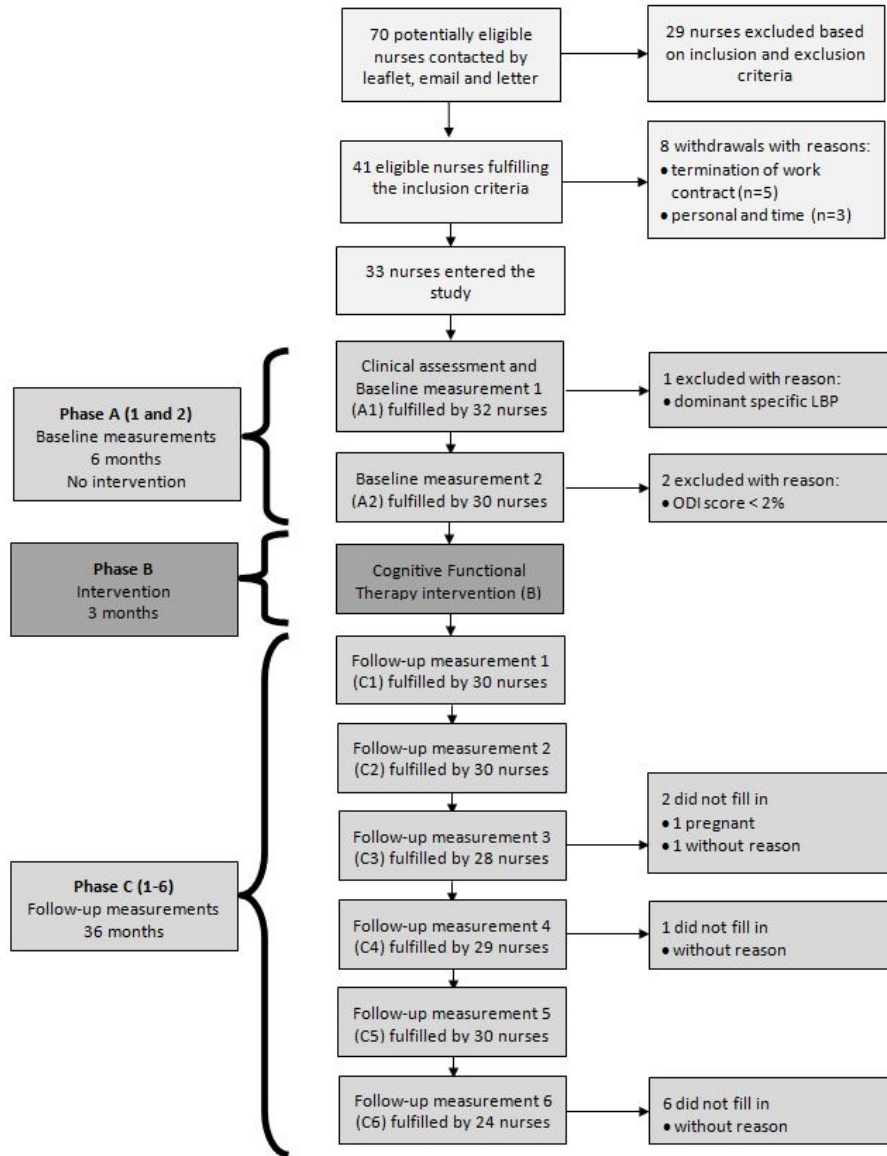
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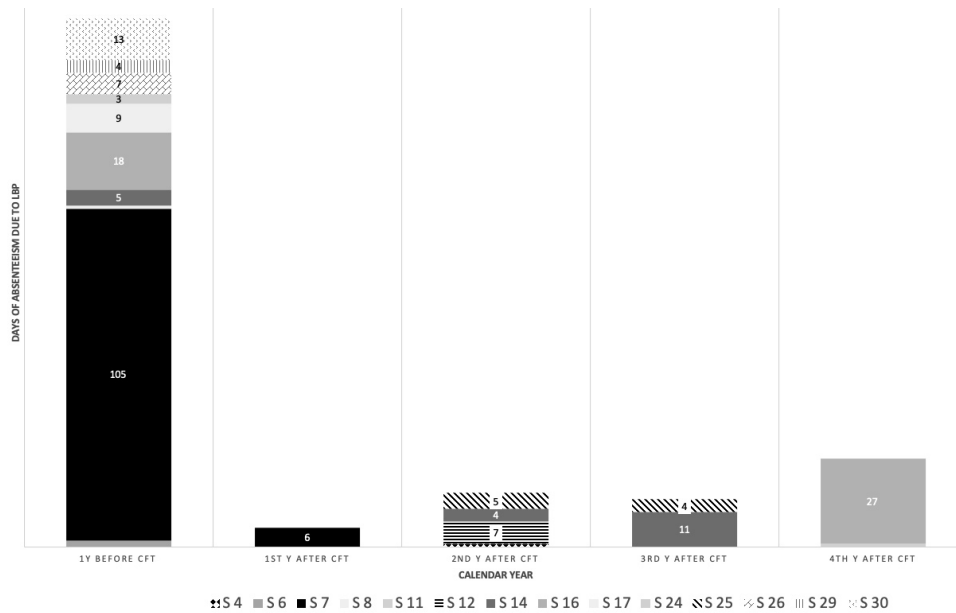
(9) Video legends

NA

(10) Appendixes

NA

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Study design and flowchart of participants.

169x219mm (96 x 96 DPI)

Days of absenteeism due to LBP per subject with absenteeism in the year before and the four calendar years after the CFT intervention.
Total days of absenteeism due to LBP were calculated per calendar year, black lines show the nurses experiencing reduced LBP-related absenteeism after CFT, black dotted lines show the nurses having reduced absenteeism after CFT and experience a flare-up, grey dotted lines show the nurses having no absenteeism before CFT but experience a flare-up, CFT: Cognitive Functional Therapy, '1y before CFT': is the year before the start of the CFT intervention, '1st y after CFT': first calendar year after A2 (so it includes the CFT intervention), '2nd y after CFT': second calendar year after the CFT intervention', '3rd y after CFT': third calendar year after the CFT intervention, '4th y after CFT': fourth calendar year after the CFT intervention, LBP: Low Back pain, S: Subject.

431x274mm (72 x 72 DPI)