The CONECSI trial: an RCT of a multidisciplinary cognitive behavioral program for coping with chronic neuropathic SCI pain

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Adelante, Hoensbroek

Background (1)

► Prevalence of SCI pain 65-85%
  1/3 severe pain (Siddall, et al., 2003; Wollaars 2007)

► Prevalence 5 years after SCI (Siddall, et al., 2003)
  • at-level pain ≈ 40%
  • below-level pain ≈ 35%

Background (2)

► Treatment is often insufficiently effective, particularly for neuropathic SCI pain (Smith & Grupstra, 2007)

► Psychosocial factors (e.g. pain cognitions) are associated with chronic neuropathic pain (Wollaars et al., 2007; Widerström-Noga, et al., 2007)

► Cognitive behavioral approach might be relevant for chronic neuropathic pain after SCI (Norrbrink Budh, et al., 2006)

The CONECSI trial

The CONECSI trial (COping with NEuropathic Spinal cord Injury pain):
“Evaluation of a multidisciplinary cognitive behavioral program for coping with chronic neuropathic pain following spinal cord injury”

Intervention (1)

► Comprising educational, cognitive, and behavioral interventions

► 10 weekly sessions (3 hours), comeback session in week 13

► Groups of ± 8 persons with SCI

► Guided by a psychologist / nurse practitioner and a physiotherapist

Intervention (2)

► Guided group discussion

► Education on SCI pain

► Education on pain coping and cognitions
  • Activating event Beliefs Consequences (ABC) model
  • BioPsychoSocial (BPS) model (capacity and load)

► Exercises and sport workshops

► Meeting with a role model

► Buddy (session 2 and 8)

► Homework assignments
**In- en exclusion criteria**

**Inclusion:**
- SCI and ≥ 18 years old
- ≥ 1 year after discharge from first SCI rehab
- Main pain type neuropathic pain
- Duration of neuropathic pain ≥ 6 months
- Pain intensity last week ≥ 40 (scale 0-100)

**Exclusion:**
- SCI by metastatic tumour
- Previous CBT for coping with pain after SCI
- Serious language problems or psychopathology

**Effectiveness of the intervention (1)**

**Primary outcome measure**
- Chronic Pain Grade questionnaire (Von Korff, et al.)
  - Pain intensity
  - Pain-related disability

**Secondary outcome measures**
- Hospital Anxiety and Depression Scale (Zigmond & Snaith)
- Utrecht Activities List (Post)
- Life Satisfaction Questionnaire (Fugl-Meyer, et al.)

**Effectiveness of the intervention (2)**

**Exploratory: Are pain coping and pain cognitions related to intervention effects?**
- Coping with Pain Questionnaire (Rosenstiel & Keefe)
- Pain Coping Inventory List (Kraaimaat, et al.)
- Pain Cognition List (Vlaeyen, et al.)

**Participant satisfaction**

**Rating of usefulness by participants**

**Identification of the elements participants think are most effective**
- Evaluation form

**Study design**

**Multicenter, Randomized Clinical Trial**
- Waiting-list control group (6 months)
- Randomization per center
- Four rehabilitation centers

**Participating rehabilitation centers**
- Enschede
- Rotterdam
- Utrecht
- Hoensbroek
Papers (1)


Papers (2)


Results t3 follow-up

Baseline data

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>57.7</td>
<td>59.9</td>
</tr>
<tr>
<td>Men</td>
<td>67.7%</td>
<td>60.0%</td>
</tr>
<tr>
<td>Married/living together</td>
<td>80.6%</td>
<td>86.7%</td>
</tr>
<tr>
<td>Median time since SCI (years)</td>
<td>5.4</td>
<td>5.0</td>
</tr>
<tr>
<td>Traumatic</td>
<td>80.6%</td>
<td>63.3%</td>
</tr>
<tr>
<td>Tetraplegia</td>
<td>35.5%</td>
<td>26.6%</td>
</tr>
<tr>
<td>Complete SCI</td>
<td>51.7%</td>
<td>20.0%</td>
</tr>
</tbody>
</table>
**Pain intensity CPG**

- Main effect time t1•t2: \( p = .009^* \)
- Main effect group: \( p = .973 \)
- Interaction•effect t1•t2: \( p = .381 \)
- Intervention group t1•t2: \( p = .019^* \)

**Pain-related disability CPG**

- Main effect time t1•t2: \( p < .001^* \)
- Main effect group: \( p = .834 \)
- Interaction•effect t1•t2: \( p = .059 \)
- Intervention group t1•t2: \( p = .002^* \)

**Anxiety score HADS**

- Main effect time: \( p = .001^* \) and \( p = .006^* \)
- Main effect group: \( p = .126 \)
- Interaction effect: \( p = .007^* \) and \( p = .032^* \)
- Interv.group t1•t2 and t1•t3: \( p = .007^* \) and \( p = .027^* \)

**Participation UAL**

- Main effect time: \( p = .019^* \) and \( p = .004^* \)
- Main effect group: \( p = .003^* \)
- Interaction effect: \( p = .005^* \)
- Interv.group t1•t2 and t1•t3: \( p = .034^* \) and \( p = .008^* \)

**Rating by participants (1)**

**Tools:**
- No (0%)
- Somewhat (75%)
- Yes (25%)

**Expectations:**
- Less than expected (25,0%)
- As expected (66,7%)
- Expectations exceeded (8,3%)

**Rating by participants (2)**

**Usefulness of the intervention**
- Not at all useful (0%)
- Somewhat useful (45.8%)
- Useful (50.0%)
- Very useful (4.2%)

**Main comments-suggestions**
- Length and frequency OK
- Would recommend it to others
- Would be useful to offer this earlier after SCI
**Most useful elements**

1) Sportworkshops 75%
2) Guest speaker on SCI pain 63%
3) Relaxation exercises 58%
4) Contact with peers 58%
5) Theory on movement and pain 58%
6) Theory on pain, mood and stress 54%
7) Theory set limits (communication) 50%
8) Goal setting 50%
9) Guest speaker on chronic pain 42%
10) The ABC-method 38%
11) Guest speaker role model 33%
12) Theory on social aspects 33%
13) Bio-Psycho-Social-model 29%
14) Theory on exercise 29%
15) Homework 8%

**Over-all rating**

► Over-all rating (10 scale): 7.6 (N=24)

- Rotterdam: 7.6 (n=7)
- Enschede: 7.4 (n=7)
- Utrecht: 7.4 (n=4)
- Hoensbroek: 8.0 (n=6)

**Conclusions**

► Effectiveness: mixed results, not very firm evidence
► But some positive effects were seen
  - 21% decrease in pain-related disability
  - Treatment effect on anxiety and participation
► Secondary analyses are ongoing
  - Baseline levels of pain
  - Baseline levels and change of pain coping and cognitions
  - Long term effects (12 months)
► Larger study might prove effectiveness of the intervention

**Collaborators**

De Hoogstraat, Utrecht:
- L. Pfennings
- P. Luthart
- F. van Asbeck & C. Dijkstra
- M. Heutink
- F. Post
- E. Lindeman

Rijndam, Rotterdam:
- H. Schors & N. Vrijens
- L. Vlemmix & J. Sweers
- D. Spijkerman

Het Roessingh, Enschede:
- M. van de Veer
- M. Schuitemaker
- G. Streek & A. Nene

Adelante, Hoensbroek:
- C. Overduine
- S. Slangen
- H. Sengers & N. Zusterzeel

De Nederlandse Organisatie Nederland
(patient organization)

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**Questions/remarks?**

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