

Identifying prognostic factors to determine the level of recovery in servicemembers with chronic low back pain: a prospective cohort study.

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Abstract

Background

In the Dutch Armed Forces (DAF), low back pain is the third most reported musculoskeletal disorder. For the prognosis of chronic low back pain (CLBP) only limited evidence is available. This observation results in a lack of clarity on prognostic factors that might affect recovery from CLBP in service members. The main objective is to identify general and military-related factors that are associated with the level of recovery in DAF service members with CLBP who followed a rehabilitation program.

Methods

One hundred five consecutive service members with CLBP who completed the rehabilitation program have been included in this prospective observational cohort study. The primary outcome measurement, level of disability, was used to distinguish a recovered and non-recovered group. Level of pain and self-perceived recovery were used as secondary outcome measurements. Disability and pain were measured at baseline and 12 weeks follow-up and self-perceived recovery only at follow-up. Differences were evaluated within and between the groups using the Student's t-test, according to the normality of the data distribution. Bivariate logistic regression analyses were used for identifying the prognostic factors related to various outcomes of recovery.

Results

After following the rehabilitation program, 64.8% of the service members recovered from CLBP. In the recovered group, there are significant effect sizes of -6.72 (CI: -7.57 - -5.87) in the level of disability and -2.58 (CI: -3.17 - -1.98) in level of pain, whereas the non-recovered group shows a non-significant effect size of -0.49 (CI: -1.27 - -0.29) in level of disability and a significant effect size of -0.94 (CI: -1.62 - -0.25) in level of pain. The self-perceived recovery in the recovered group is on average "much improved" and in the non-recovered group "slightly improved". The results of the bivariate regression analyses show no significant independent prognostic factors related to recovery.

Conclusion

In this study, no significant independent prognostic factors could be identified that are associated to the various outcomes of recovery in service members with CLBP who followed a rehabilitation program.

Background

In the Dutch Armed Forces (DAF), low back pain is the third most reported musculoskeletal disorder following knee and lower extremity injuries.[1] Among active military members of the US Army between

2011 and 2014, over 6 million medical encounters with the diagnosis of low back pain and two-thirds of the outpatient visits were labelled chronic low back pain (CLBP).[2] CLBP causes high medical costs as well as a socio-economic burden due to high absence from work. In the US Army, low back pain has been demonstrated to be the highest cumulative risk of disability discharge and is a common reason for causing medical evacuation.[3, 4] For the DAF, these figures are not available however, it is reasonable to believe that they are comparable with the situation in the US.

On that account, more and more research is being performed about the prognosis of CLBP to improve prevention as well as achieving to find more matching effective treatments. However, a recent systematic review shows that only limited evidence is available with regard to the prognosis for recovery and that the overall quality of the studies is low.[5] Also, a broad variety of prognostic variables have been found due to the high degree of heterogeneity in the CLBP population.[6] Thus, it is important to distinguish different subgroups within the CLBP population by identifying the associated prognostic factors for recovery, which may improve intervention effectiveness.[7]

At present, limited research is available on the prognostic factors specific to service members with CLBP. [8] It is not clear which prognostic factors affect recovery from CLBP in service members following a multidisciplinary therapy program and whether this program frames matching treatment for this subgroup. The contribution of this study to the body of knowledge will be the military setting.

The objective of this study is to identify general and military-related factors that might be associated with the level of recovery in DAF service members with CLBP who followed a rehabilitation program, as well as to evaluate whether military-related factors add to the general prognostic factors.

Methods

Subjects and setting

This prospective cohort study included consecutive servicemembers with CLBP who followed a multidisciplinary program at the Military Rehabilitation Centre (MRC), Doorn, the Netherlands, from September 2016 and November 2018. The servicemembers were referred by either a general practitioner of the military health centre at their unit or a medical specialist of the Central Military Hospital in Utrecht.

A participant was included in the study if the low back pain (with or without leg pain) was non-specific for a duration of more than 3 months and the individual was in active duty with the DAF. Before the start of treatment, CLBP was diagnosed in a triage setting at the MRC by a rehabilitation physician, manual therapist and a psychologist. Patients were excluded from this study in cases of manifestation of neurological or rheumatological problems, stenosis complaints, multiple diseases, pregnancy, psychiatric or primary psychological problems and drugs and/ or alcohol abuse.

The multidisciplinary rehabilitation program consisted of a 12-weeks treatment period, 3 days per week and included the following elements: physical therapy (2 times 30 minutes per week), occupational

therapy (1 time 30 minutes per week), sports therapy (3 times 60 minutes per week), social work (1 time 30 minutes per 2 weeks), psychology (1 time 60 minutes per 2 weeks) and vocational therapy (2 times 30 minutes per week). All therapists used a biopsychosocial treatment approach, in which a time-focused, gradual increase of activity was the main focus/option. Whereas, the biological and physical aspects were covered by the physical therapist, occupational therapist and sports therapist. Psychosocial aspects of the treatment were mainly covered by the social worker and psychologist. At the end of the rehabilitation program, further build-up of physical capacity for duty was advised, either independent at their unit or under supervision of coaches at the MRC. All participants provided written informed consent. The Central Commission Medical Research (CCMO) confirmed that this study did not require ethical approval because the protocol was 'Care As Usual' (CAU). The Dutch Defence Health Organization also approved this study (DGO170616006).

Prognostic variables

As stated in other literature, the prognostic factors for this study related to biopsychosocial factors that are associated with CLBP and are distinguished in general and military-related factors (Table 1).[9]The general factors were derived from recent studies that showed a prognostic value on recovery from CLBP. [10] The military-related factors were based on our clinical experience and relevant for the military population.

At the MRC, the general factors were extracted from validated and reliable questionnaires before the start of treatment and, in addition, the military-related factors have been measured by a questionnaire at baseline.

| Table 1. Prognostic variables | |
|--|--|
| General factors | Measurement properties |
| Self-efficacy | Pain Self Efficacy Questionnaire (PSEQ) shows the confidence in the ability to perform tasks despite the pain. Scores range from 0 to 60, whereas higher scores reflect stronger self-efficacy beliefs.[11] |
| Psychological distress - total score - anxiety symptoms - depression symptoms - somatisation symptoms | Symptom CheckList-90-R (SCL-90-R). A 90-item self-report symptom inventory that measures psychological symptoms and psychological distress, the SCL-90-R has nine symptom dimensions: anxiety, agoraphobia, depression, somatization, insufficiency, sensitivity, hostility and insomnia. Each of the 90 items is rated on a five-point Likert scale, ranging from 'not at all' to 'extremely'. [12] |
| Level of disability | Roland Morris Disability Questionnaire (RMDQ) consists of 24 items representing physical activities that are likely to be affected by low back pain. Range of score is 0 to 24, where a higher score means more disability.[13] |
| Level of pain | Numeric Pain Rating Scale (NPRS). An 11-point scale that measures pain intensity, where '0'= no pain and '10'= worst possible pain.[14] |
| Military-related factors | |
| Basic military physical test | The basic military physical test (DCP) consists of three elements: a 12-minute run, push-ups and sit-ups. The ability to complete the test was measured dichotomously (positive/negative). |
| Cluster level | Reflects the physical requirements of military functions, ranging from cluster 1 'administrative work' to cluster 6 'high physical work'. Measured dichotomously ('cluster 1-3' and 'cluster 4-6'). |
| Duration of military service | Measures how long the participant has worked in the DAF and is measured dichotomously ('0-10 years' and '10 > years'). |

Outcome measures

The primary outcome measure was the level of functional disability measured by the RMDQ. A decrease of > 30% between baseline and follow-up measurement was adopted as a cut-off point for the classification of recovered and non-recovered.[15] Functional disability as primary outcome was chosen because increasing activity and reducing disability are the main objectives of the rehabilitation program and because functional disability is one of the most relevant core outcome domains in CLBP.[15, 16] Based on clinical experience, the study population has on average a low baseline score resulting in the use of a relative score as the criterion instead of an absolute score.

The secondary outcome measurements were level of pain and self-perceived recovery, respectively measured with the Verbal Rating Score (VRS) and the Global Perceived Effect Questionnaire (GPE). [14, 17] At baseline and follow-up, the VRS was recorded after a 1 km run at a comfortable speed. The VRS is the verbal equivalent of the NPRS.[17] The classification of recovery after the MRC rehabilitation program was set at a decrease of $\geq 30\%$ of the VRS.[15] The GPE, a 7-point transition scale that reflects the patient's perception of recovery, was completed by the participant at follow-up, where 'clinically improved' was scored as category 1 (fully recovered) or category 2 (much improved). The remaining categories were considered 'unchanged' in level of recovery.[18]

Statistical analysis

To describe the characteristics and prognostic factors of the participants at baseline, means and standard deviations (continuous variables) as well as counts and frequencies (categorical variables) were calculated in the recovered and non-recovered group. To evaluate any demographic differences between the two groups, corresponding p-values were calculated with the Student's t-test, Chi-square test or Fisher exact test, according to the measurement level.

All outcome measurements, at baseline and follow-up were used to calculate the number and percentages of recovered and non-recovered participants in the two groups. Also, the group means including the standard deviation were evaluated with corresponding effect sizes and p-values within the group and between the recovered and non-recovered group based on the primary outcome measurement using the Student's t-test or Mann-Whitney U test.

To evaluate the magnitude of prognostic factors, bivariate logistic regression analyses were performed on the primary and secondary outcome variables from which odds ratios (ORs) and 95% confidence intervals (CIs) were calculated. All analyses were performed using R software version 3.2.3 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Between September 2016 and November 2018, a total of 278 patients were screened in the triage setting at the rehabilitation intake (Fig. 1). Of the 116 included patients with CLBP, 105 participants completed the multidisciplinary program, and their data were used for the analysis. The descriptive statistics and baseline measurement of prognostic factors are presented in Table 2. No significant differences between the two groups on patient characteristics were obtained. For efficiency and reliability of estimates, multiple imputations chained equations (MICE) was performed for missing data (4,1%). The outcome variables level of pain and self-perceived recovery have the highest percentage of missing data, however they are missing completely at random (MCAR) or missing at random (MAR).

| Table 2. Demographic characteristics and prognostic variables at baseline between recovered and non-recovered group | | | |
|--|---------------------------------|-------------------------------------|----------------|
| Characteristics | Recovered group N=68 | Non-recovered group N=37 | P-value |
| Age (years, $\bar{x} \pm$) | 35.26 (10.49) | 35.59 (11.01) | 0.880 # |
| Male (n %) | 65 (95.60) | 32 (86.49) | 0.126 \$ |
| Residency (n %) | | | 0.22 \$ |
| Clinical | 26 (38.24) | 19 (51.35) | |
| Outpatient | 42 (61.76) | 18 (48.65) | |
| Period treatment (weeks, $\bar{x} \pm$) | 10.38 (2.59) | 9.97 (1.76) | 0.392 # |
| Body weight (kg, $\bar{x} \pm$) | 90.60 (13.44) | 85.36 (13.30) | 0.062 # |
| Smoking (yes, n %) | 26 (38,24) | 10 (27,03) | 0.287 \$ |
| Partner (yes, n %) | 57 (83,82) | 30 (81,08) | 0.789 \$ |
| Sport (n %) | | | 0.186 * |
| Military sport | 6 (8.82) | 7 (18.92) | |
| Fitness | 22 (32.35) | 14 (37.84) | |
| Ball sport | 4 (5.88) | 1 (2.70) | |
| Biking | 11 (16.18) | 1 (2.70) | |
| Running | 11 (16.18) | 4 (10.81) | |
| Other | 8 (11.77) | 8 (21,62) | |
| No sports | 6 (8.82) | 2 (5.41) | |
| Military service (n %) | | | 0.420 * |
| Army | 35 (51.47) | 21 (56.76) | |
| Air force | 13 (19.12) | 7 (18.92) | |
| Navy | 12 (17.65) | 2 (5.40) | |
| Military police | 8 (11.76) | 7 (18.92) | |
| Other complaints (yes, n %) | 24 (35.29) | 18 (48.65) | 0.214 \$ |
| Work reduction (yes, n %) | 16 (23.53) | 11 (29.73) | 0.642 \$ |
| Previous treatment (yes, n %) | 43 (63.24) | 28 (75.68) | 0.275 \$ |
| Prognostic variables | | | |
| Specific military-related factors | | | |
| Ability to execute DCP (yes, n %) | 31 (45.59) | 18 (48.65) | |
| Cluster level (n %) | | | |
| 1-3: mild physical work | 44 (64.71) | 25 (67.57) | |
| 4-6: intensive physical work | 20 (29.41) | 9 (24.32) | |
| Duration of military service (n %) | | | |
| < 10 years | 24 (35.29) | 16 (43.24) | |
| > 10 years | 44 (64.71) | 21 (56.76) | |
| General factors | | | |
| Self-efficacy (PSEQ, $\bar{x} \pm$) | 43.30 (10.41) | 39.63 (12.19) | |
| Psychological distress (SCL-90-R, m range): | | | |
| Total score | 117 (94-256) | 119 (89-220) | |
| Anxiety symptoms | 12 (9-25) | 12 (10-26) | |
| Depression symptoms | 19 (16-50) | 19.5 (15-49) | |
| Somatisation symptoms | 20 (14-41) | 20.5 (12-36) | |
| Level of disability (RMDQ, m range) | 9 (1-19) | 9 (2-20) | |
| Level of pain (NPRS, m range) | 7 (0-10) | 7 (3-9) | |

Primary and secondary outcomes

The mean of the primary outcome measure at baseline is lower in the non-recovered group, and the degree of pain is higher compared with the recovered group; however, the differences are not significant (Table 3). The effect size within the recovered group on the level of disability is -6.72 (CI: -7.57 - -5.87) with a significant p-value of < 0.0001. Within the non-recovered group, the effect size is -0.49 (CI: -1.27 - -0.29) with a p-value of 0.2143. The difference in change score between the two groups is significant (p-value < 0.0001). For the degree of pain, the effect size for the recovered group is -2.58 (CI: -3.17- -1.98) with a p-value of < 0.0001, whereas the non-recovered group also shows a significant effect size of -0.94 (CI: -1.62 - -0.25) with a p-value of 0.009. Nevertheless, it results in a significant p-value between the mean change scores of the two groups (p-value 0.0008). The self-perceived recovery in the recovered group is on average “much improved” and in the non-recovered group “slightly improved”.

| Table 3. Outcome measurements recovered and non-recovered patients | | | | | |
|--|---------------------------------------|-----------------------------|---|-----------------------------|-----------------------|
| Recovered and non-recovered patients based on the outcome measurements | | | | | |
| | Recovered group (n %) | | Non-recovered group (n %) | | Missing data (n %) |
| Level of disability (RMDQ) | 68 (64.77) | | 37 (35.24) | | 0 (0) |
| Level of pain (NPRS) | 54 (51.43) | | 30 (28.57) | | 21 (20) |
| Perceived recovery (GPE) | 48 (45.71) | | 31 (29.52) | | 26 (24.76) |
| Baseline and follow-up outcome measurements in recovered and non-recovered group | | | | | |
| | Baseline N=105 \bar{x} (\pm) | | 9-12 weeks follow-up N=105 \bar{x} (\pm) | | |
| | Recovered group N=68 | Non-recovered group N=37 | Recovered group N=68 | Non-recovered group N=37 | |
| Level of disability (RMDQ) | 9.84 (4.31) | 9.32 (5.13) | 3.12 (2.58) | 8.84 (4.15) | |
| Level of pain (NPRS) | 4.28 (2.36) | 4.86 (2.76) | 1.84 (2.08) | 3.97 (2.65) | |
| Perceived recovery (GPE) | | | 2.21 (0.50) | 2.96 (0.74) | |

Prognostic factors

The results of the bivariate logistic regression analysis performed on the primary outcome shows that in servicemembers with CLBP, no independent prognostic factors on recovery in functional disability can be identified (Table 4). An identical finding is derived from the bivariate logistic regression on the classification of recovery in pain and in self-perceived recovery in back complaints (Table 4). The OR's of almost all prognostic variables are not consistent < 1 or > 1 per outcome measurement, except for the variable level of pain. With all outcome measurements, the OR of level of pain is consistent < 1.

| Table 4. Bivariate logistic regression analyses | | |
|--|--------------------|----------------|
| Bivariate logistic regression analysis on primary outcome measurement (RMDQ) | | |
| | OR (95% CI) | P-value |
| Ability to execute DCP | 1.13 (0.50-2.55) | 0.765 |
| Cluster level | 0.72 (0.31-1.64) | 0.425 |
| Duration of military service | 0.79 (0.31-2.03) | 0.623 |
| Self-efficacy (PSEQ) | 1.03 (0.99-1.07) | 0.134 |
| Psychological distress (SCL-90-R): | | |
| Total score | 0.997 (0.98-1.01) | 0.705 |
| Anxiety symptoms | 0.96 (0.87-1.07) | 0.506 |
| Depression symptoms | 1.00 (0.95-1.06) | 0.967 |
| Somatisation symptoms | 0.98 (0.91-1.06) | 0.597 |
| Level of disability (RMDQ) | 1.02 (0.93-1.11) | 0.689 |
| Level of pain (NPRS) | 0.94 (0.76-1.17) | 0.608 |
| Bivariate logistic regression analysis on secondary outcome measurement (NRS) | | |
| | OR (95% CI) | P-value |
| Ability to execute DCP | 0.67 (0.27-1.67) | 0.382 |
| Cluster level | 0.77 (0.31-1.94) | 0.573 |
| Duration of military service | 0.61 (0.21-1.74) | 0.352 |
| Self-efficacy (PSEQ) | 0.99 (0.95-1.04) | 0.648 |
| Psychological distress (SCL-90-R): | | |
| Total score | | 0.199 |
| Anxiety symptoms | 1. (0.99-1.03) | 0.186 |
| Depression symptoms | 1.10 (0.95-1.26) | 0.239 |
| Somatisation symptoms | 1.04 (0.97-1.13) | 0.643 |
| | 1.02 (0.93-1.12) | |
| Level of disability (RMDQ) | 1.01 (0.92-1.12) | 0.820 |
| Level of pain (NPRS) | 0.93 (0.70-1.24) | 0.637 |
| Bivariate logistic regression analysis on secondary outcome measurement (GPE) | | |
| | OR (95% CI) | P-value |
| Ability to execute DCP | 0.94 (0.37-2.35) | 0.889 |
| Cluster level | 1.15 (0.43-3.05) | 0.773 |
| Duration of military service | 1.05 (0.36-3.04) | 0.931 |
| Self-efficacy (PSEQ) | 1.02 (0.98 -1.07) | 0.321 |
| Psychological distress (SCL-90-R): | | |
| Total score | 0.99 (0.98-1.01) | 0.936 |
| Anxiety symptoms | 1.04 (0.92-1.18) | 0.512 |
| Depression symptoms | 1.00 (0.94-1.08) | 0.894 |
| Somatisation symptoms | 0.97 (0.87-1.07) | 0.501 |
| Level of disability (RMDQ) | 0.98 (0.89-1.08) | 0.761 |
| Level of pain (NPRS) | 0.87 (0.68-1.11) | 0.257 |

Discussion

The objective of this study was to identify general and military-related factors associated with the level of recovery in service members with CLBP who have followed a rehabilitation program, as well as to

investigate whether military-related factors add to the general prognostic factors.

The result of this study shows no significant independent prognostic factors that determine the level of recovery from CLBP despite the more homogeneous population of service members. The explanation could be that the degree of homogeneity within the military group with CLBP is still too low, which prevents identification of a subgroup with equal prognosis. Also, in the general CLBP population, it is challenging to find strong independent prognostic factors due to a high degree of heterogeneity, as well as various outcomes and interventions and use of low methodological quality studies.[5, 19]

In this study, level of disability is used as a prognostic factor and primary outcome measurement, both measured with the RMDQ. Due to the use of a relative score as criterion for recovery, it is common that an association occurs with the baseline score as prognostic factor. This is because participants with a high baseline score have to decrease a larger number of points to recover compared to participants with a low baseline score. This association is also seen in a study by Verkerk[9], where a higher disability at baseline is a significant prognostic factor for > 30% improvement in recovery (Quebec Back Pain Disability Scale). This leads to the conclusion that further research should either use an absolute score as criterion for recovery or use a different outcome measurement, for example "return to work", with respect to the prognostic factor.

An association between psychosocial factors and level of recovery is not detected by this study, however, reported in a systematic review, reasonable evidence indicates symptoms of distress, depression and somatization as prognostic factors.[20, 21] Regrettably, there is still a lack of knowledge about the mechanism that influences the relationship between depression and CLBP. It is unclear which of the problems causes the other, but if both exist, there is an impact on the prognosis.[21] Therefore, addressing symptoms of depression in the treatment might have a positive effect on the level of recovery from CLBP. Other studies show that a higher self-efficacy at baseline increases the risk of non-recovery from CLBP.[22–25] This can result in modifying the content of the rehabilitation program which could put more emphasis on increasing self-efficacy for the purpose of reducing disability. However, it is mentioned in a systematic review of Tseli, et al, treatment should not only target on negative psychological factors, yet also increase focus on positive protective factors which are associated with a better prognosis.[26]

By lack of identifying significant prognostic factors in this study, a multivariate analysis for building a prediction model was not conducted. The sample size of this study is probably too small to detect significance. For further research, the study results can be used for a power analysis to calculate an appropriate sample size. A larger sample might provide further evidence for identifying prognostic factors associated with the level of recovery of CLBP in service members and the ability to perform a multivariate analysis.

Furthermore, the results show that the military-related factors have no significant contribution to predict the level of recovery from CLBP in addition to the general factors, which may be caused by using non-validated questionnaires or improperly used cut-off points. To our knowledge, there is limited literature about specific military-related factors predicting the recovery or course of CLBP. Most research within the

army is focused on risk factors of low back pain.[27] Therefore, more research is needed about military-related factors that may affect the course of CLBP in the military population.

In this study, almost 65% of the service members recovered from CLBP after a rehabilitation program. In two systematic reviews, it also shows that multidisciplinary treatment, compared with usual care and physical treatment, decreases short-term recovery in disability to a moderate degree.[28, 29] However, Ravenek concluded in his review that there is no effect on the level of disability.[30] This conflicting evidence could be attributed to difference in content of treatment, difference in outcome classification, or heterogeneity of the CLBP population. This study sample differs from the general CLBP population, since there is a notable difference in gender, age and work reduction.[30] This difference may be the result of the military setting, in which there are a higher number of males and adolescents. Moreover, in this study a relative score of greater than 30% on the RMDQ has been used for the classification of recovery, which varies from other literature using absolute differences or using the Oswestry Disability Index (ODI). [16, 29] This difference could also affect the proportion of recovery.

This research presented several limitations that may affect the results. First, only short-term measurements are used for the classification of recovery. The lack of long-term follow-up means that we cannot be certain whether the results apply to long-term recovery of CLBP as well. However, it has been noted that the course of recovery also improves after 12 weeks up to 1 year, albeit slower than in the first 6 weeks.[31] Moreover, the choice for disability as primary outcome measurement does not mean that recovered service members are also able to return to work, because a military job often requires a higher physical load capacity. Second, the content and length of treatment per participant in this study was not consistent. This difference could lead to bias(i.e., the level of recovery) however, two randomized controlled trials showed that there is no extensive difference in effect due to different intensity of treatment.[32, 33] Finally, the findings of this study are restricted to the military population with CLBP and cannot be taken as evidence for the entire population of patients with CLBP.

Conclusion

In this study, no significant independent prognostic factors could be identified to determine the level of disability, level of pain or self-perceived recovery in service members with CLBP who have followed a rehabilitation program. Also, the military-related factors have no additional contribution to predict the level of recovery. A larger sample might provide further evidence for identifying general and military-related factors. For future research, we also suggest to use long-term outcomes, as well as involving “return to work” and possibly considering other military-related factors.

Abbreviations

CAU: Care As Usual; CCMO: Centrale Commissie Mensgebonden Onderzoek; CI: Confidence interval; CLBP: Chronic Low Back Pain; DAF: Dutch Armed Forces; DCP: Defence Condition Proof; DGO: Defensie Gezondheidszorg Organisatie; GPE: General Perceived Effect; MAR: missing at random; MCAR: Missing

Completely At Random; MICE: Multiple Chained Equations; MRC: Military Rehabilitation Center; NPRS: Numeric Pain Rating Scale; OR: Odds Ratio; PSEQ: Pain self-efficacy questionnaire; RMDQ: Rolland Morris Disability Questionnaire; SCL-90-R: Symptom Coping List-90-Revised; VRS: Verbal rating scale.

Declarations

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Availability of data and materials

All relevant data are presented in the text and the tables.

Authors' contributions

BPMM is responsible for the study design, data collection, statistical analysis of the data, and article preparation; MZM contribute to the study design, statistical analysis of the data, and article preparation; PvdW contributed to the study design, statistical analysis of the data, and article preparation; CL contributed to the study design, statistical analysis of the data, and article preparation. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Ethical approval for prospective anonymous assessment of the data was obtained by a waiver from the Central Committee for Human Research (CCMO) of the Netherlands and Defence Health Organization (DGO) no.170616006, the Netherlands.

Consent for publication

Not applicable.

Competing interests

The authors declare that there are no conflicts of interest according to the guidelines of the International Committee of Medical Journal Editors.

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Figures

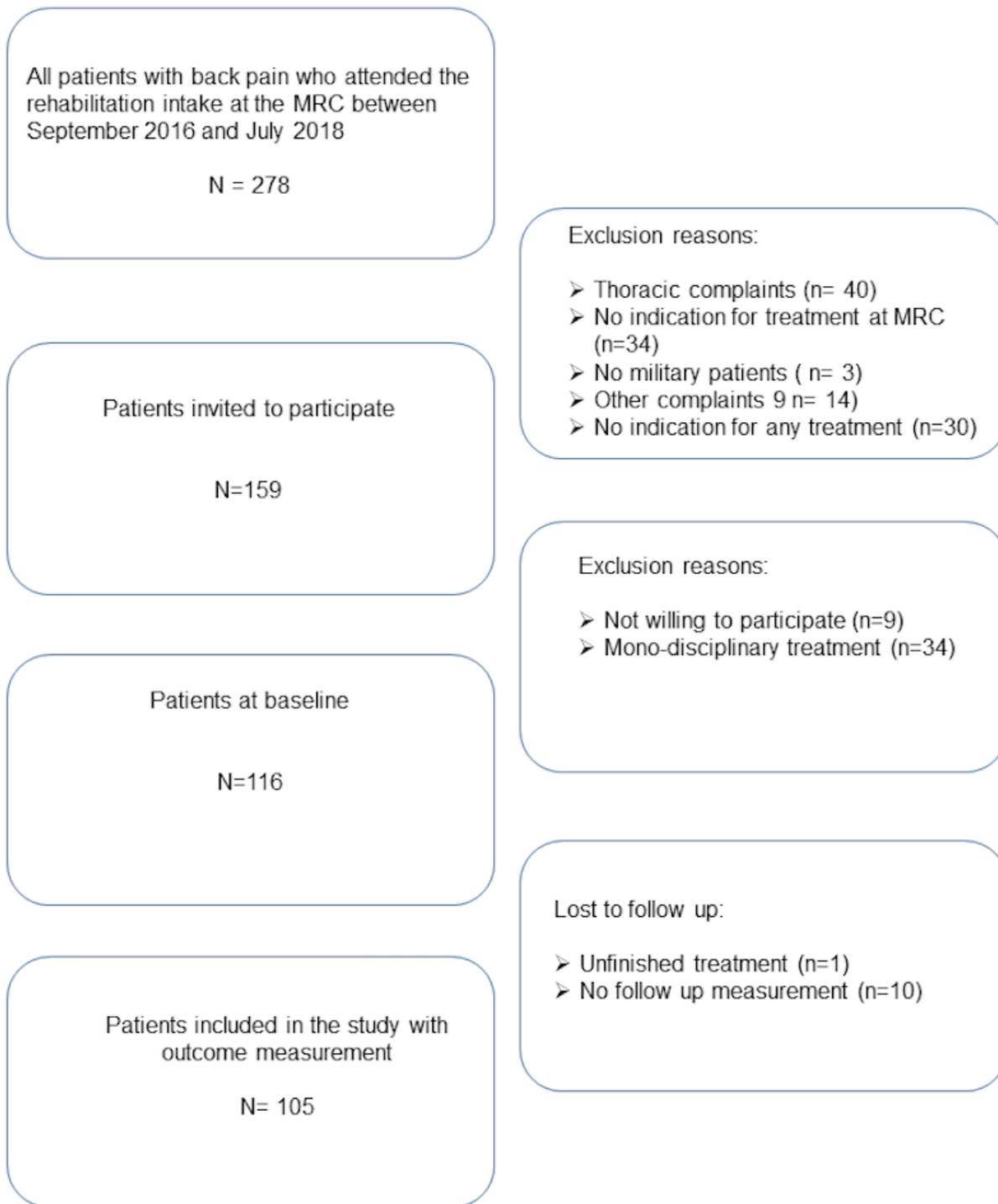


Figure 1

Flow chart of study population.