

Reassuring Patients With Low Back Pain in Primary Care Consultations

Does it Happen, and Does it Matter? A ChiCo Cohort Study

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Objectives: Reassurance is an important part of treatment for low back pain (LBP). The Consultation-based Reassurance Questionnaire measures patients' perceived reassurance after health care consultations on 4 subdomains (ie, Data-gathering, Relationship-building, Generic reassurance, Cognitive reassurance). The objectives of this study were to investigate associations between the level of reassurance and outcomes and to investigate if the associations were moderated by patients' risk profile.

Materials and Methods: Adult patients consulting chiropractors for LBP were emailed the Consultation-based Reassurance Questionnaire directly after the consultation. Outcomes were Global Perceived Effect (GPE) after 2 weeks, and pain (Numeric Rating Scale) and disability (Roland-Morris Disability Questionnaire) 2 weeks and 3 months following treatment. Associations with GPE were tested in logistic mixed models. Associations between each reassurance domain and pain and disability were tested in longitudinal analyses using linear mixed models. Moderations by risk profile were tested by introducing an interaction between risk groups and reassurance level. All models were controlled for several potential confounders.

Results: A total of 2056 patients were included in the study, with 46% reporting LBP for less than a week. Associations between reassurance level and improvement in LBP intensity and disability

were weak but positive, whereas associations with GPE were potentially clinically relevant. None of the associations were moderated by psychological risk profile.

Discussion: Identified associations between reassurance and outcomes were weak, however, for GPE the association might be of a clinically relevant magnitude. The causal relationship is unclear, but with communication always present in a consultation these results suggest that efforts to optimize clinician-patient communication might be worthwhile, also for people with very recent onset of LBP.

Key Words: back pain, reassurance, primary care, psychological risk
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Nonspecific low back pain (LBP) is a symptom that affects a very large number of people every day, and it is a leading cause of disability and for people to seek care worldwide.^{1–3}

Clinical guidelines for LBP recommend reassuring patients that acute episodes of LBP have a favorable prognosis and that LBP is not a serious illness.^{3–7} More generally, reassurance has been defined as behaviors carried out by the practitioner with the intention to reduce worry and facilitate change in the patient's illness-related behaviors, understanding, or thoughts.⁸ Qualitative research suggests that people with LBP value explicit information that would help them manage their problem, that their concerns are reduced from explanations about their problem, and that patients appreciate clinicians' affective behaviors.^{9,10} However, the evidence guiding how reassuring information is best provided is limited.^{8,11,12}

In 2016, the Consultation-based Reassurance Questionnaire (CRQ) was developed to measure reassurance during LBP consultations.¹³ It provides a tool to systematically evaluate patients' responses to clinician-provided reassurance, including associations between reassurance strategies or clinician skills and level of perceived reassurance in patients,¹⁴ as well as between level of perceived reassurance and outcomes.

The CRQ includes 4 subscales of reassurance described as data-gathering, relationship-building, generic reassurance, and cognitive reassurance. In short, data-gathering is focused on the patient feeling listened to and the perception of having had the opportunity to voice his or her concerns about the symptoms. Relationship-building is about whether the patient feels that the clinician shows a genuine interest in the present problem and an understanding of the patient's concerns. Generic reassurance is about the extent to which the clinician supports the patient emotionally by telling not to be worried, that everything will be fine, and by reassuring that there are no serious concerns about the patient's health. Cognitive reassurance focuses on the

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The data collection was approved by the Danish Data Protection Agency as part of the University of Southern Denmark's joint registration (Journal no. 2015–57-0008). All patients were informed about the project and their rights and provided informed consent that data would be used for research purposes. According to Danish law, the study did not require research ethics approval (Research Ethical Committee for Region of Southern Denmark journal no. S-20162000-109).

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information given by the clinician to the patient on how the treatment will help ease the back problem and includes checking whether the patient understands this information. Relationship-building and generic reassurance are considered elements of affective reassurance.¹³

The possible impact of reassuring information on patient outcomes has been only sparsely investigated in LBP. In a study from general practice, a high level of cognitive reassurance was associated with higher LBP intensity after 3 months, whereas high generic reassurance was associated with lower pain. Moreover, a high level of generic reassurance was associated with lower depression scores in patients with an uncomplicated profile (low risk of poor prognosis), but with higher depression scores for patients with more complex LBP, indicating that reassurance strategies might need to be tailored to a patient's psychological risk profile. The study also found a strong association between higher levels of perceived reassurance and increased satisfaction post consultation.¹⁵ Similarly, we have previously demonstrated a positive association between all 4 subscales of the CRQ and LBP patients' satisfaction with care in a chiropractic setting, and a weak positive association between generic reassurance and perceived pain control 2 weeks after an LBP consultation.¹⁶ However, 2 recent randomized trials did not demonstrate improved outcomes from systematically reassuring patients with LBP and addressing their worries.^{17,18}

The objective of this study was to further investigate relationships between levels of reassurance and patient outcomes. Specifically, the study investigated the association between reassurance measured by the 4 CRQ-subcales and outcomes of pain, disability, and Global Perceived Effect (GPE) in a large primary care cohort while accounting for a number of potential confounders. Also, it investigated if this association differed between groups of patients with different risk profiles as measured by the STarT Back Screening Tool (SBST).

MATERIALS AND METHODS

This study was a prospective cohort study based on the Danish Chiropractic back pain Cohort (ChiCo).¹⁹ The study sample was recruited from November 1, 2016, to December 21, 2018, and includes partly the same sample as our previous study on the feasibility of the CRQ recruited from November 1 2016 to October 31, 2017.¹⁶ ChiCo included patients visiting 1 of 50 chiropractors at 10 clinics in the Central Denmark Region with a new episode of LBP and followed participants for 12 months, with the present study using data from 2 weeks and 3 months follow-up. In Denmark, patients can visit a chiropractor without any referral and a proportion of the payment (~20%) is reimbursed for all patients by the national health services.

Participants

Patients visiting a chiropractor with nonspecific LBP or LBP with radiculopathy of any duration could be included in ChiCo if they started a new course of treatment, were at least 18 years old, Danish speaking, and had access to an email account. A new course of treatment was defined as contacting the clinic for an LBP problem for which they were not in an ongoing course of treatment or long-term management. Patients were excluded if the LBP was suspected to be caused by potential serious pathology or if there was a need for immediate referral for surgery. Patients were also excluded if a specific pathology causing LBP was diagnosed after participation had started.

Data Collection

The first part of the baseline questionnaire, including the written consent to participate in the project, was completed electronically on an iPad by the patients before the first consultation. A second part of the baseline questionnaire, including the CRQ, was sent to the patients' email account directly after the consultation as a link to an electronic survey. One or 2 days later, a research assistant called the patients to welcome them into the study, answer any questions about participation, and make sure they had received the second part of the baseline questionnaire. If a patient did not answer the phone call after several attempts, a message was left on the answering machine and a standard welcome-SMS was sent.

Electronic follow-up questionnaires were emailed 2 weeks and 3 months (13 wk) after inclusion. If a patient did not respond within 2 weeks, the same procedure for phone calls and SMS contact as at baseline was performed. From 30 November 2017 onwards, the phone contact for non-responders at 3-month follow-up was expanded to include interviewing participants about a few key outcomes, including LBP intensity in case the survey was not completed following the reminder.

The electronic data capture software REDCap was used to collect data. It is licensed by Odense Patient data Explorative Network (OPEN).²⁰

Baseline Information

In the first part of the baseline questionnaire the patients answered questions about age and sex; LBP intensity (0 to 10 Numeric Rating Scale, 0=no pain and 10=worst possible pain)²¹; episode duration (1 to 2 d, 3 to 7 d, 1 to 2 wk, 2 to 4 wk, 1 to 3 mo, 3 to 12 mo, >12 mo); pain control was measured by a single coping item from the Örebro Musculoskeletal Pain Questionnaire (The Danish version asking "Given an average day, to what extent can you handle or control your pain?" [0=Can't control at all, 10=Can control it completely])²²; LBP related disability by the 23-item Roland-Morris Disability Questionnaire²³ converted to a 0 to 100 scale²⁴ (0=no disability, 100=completely disabled); and the 9-item SBST determining the patients' risk profile (low, medium, high risk of poor prognosis).²⁵

In the second part of the baseline questionnaire the patients answered questions about their education level (no education, primary school, youth education, vocational training, short further education 2 to 3 y, middle further education 3 to 4 y, higher education >4 y); if they had previously had chiropractic care for LBP (yes/no); and they completed the CRQ. The 12 CRQ items cover 4 subscales (each with 3 items): Data-gathering, Relationship-building, Generic reassurance, and Cognitive reassurance. Each item is answered using a Likert scale from 0 to 6 (0=not at all, 6=a great deal)¹³ with a total score for each subscale ranging from 0 (no perceived reassurance) to 18 (highest extend of perceived reassurance).

Outcomes

The 2 weeks and 3 months follow-up questionnaires repeated the questions on LBP intensity and disability. In addition, a question about the GPE with 7 response options (much worse, worse, slightly worse, almost the same, slightly improved, improved, much improved)²⁶ was part of the 2 weeks follow-up questionnaire. For the analyses, *improved* was defined as answering improved or much improved to the GPE question.

Analyses

On the basis of the type and distribution of the variables patient characteristics were described as means with SD, medians with interquartile range, or proportions.

Before additional analyses were conducted observations were dropped if >6 of 12 items were missing on the CRQ. To impute other missing items, chained multiple imputations based on all baseline variables including the CRQ items were used. One of 5 imputed datasets for the analyses was extracted for the following analyses because only a small number of items were missing (maximum 1% missing on any CRQ item). Histograms were used to show the distribution of scores of the 4 CRQ-subcales.

Associations between the CRQ-subcales and LBP intensity and disability at 2 weeks and 3 months follow-up were tested in longitudinal analyses using linear mixed models (restricted maximum likelihood estimation) with random effects of individuals and clinics. Because of nonlinear relationships, associations between the CRQ-subcales and GPE were tested in logistic mixed models with quartiles of CRQ-subcales as the independent variable and random effects of clinics. To assist the interpretation of the associations plots were presented showing predicted outcomes for quartiles of CRQ scores.

Potential effect moderation by risk profile was investigated by introducing an interaction between SBST risk

groups and CRQ-subcales to models using Numeric Rating Scale and Roland-Morris Disability Questionnaire at 3 months follow-up, and for GPE at 2 weeks follow-up as dependent variables. Variables included as potential confounders based on the rationale that these may affect both reassurance and outcome were sex, age, education level (no qualification, vocational education, short further qualification 2 to 3 y, education 3+ y, other), episode duration (< 1 wk, 1 to 4 wk, 1 to 3 mo, 3 to 12 mo, > 12 mo), pain control and previous chiropractor visits due to LBP. All analyses were performed using Stata/IC 16.0 (StataCorp LLC, TX).

RESULTS

Study Sample

A total of 2848 patients were included in ChiCo and 2083/2848 (73%) patients completed the second part of the baseline questionnaire. Of these, 35 patients did not answer 6 or more items of the CRQ and were thus excluded resulting in a study sample consisting of 2048 patients. From this study sample, 1801/2048 (88%) of patients responded to the 2 weeks follow-up questionnaire, and 1653/2048 patients (81%) responded to the 3 months follow-up questionnaire or phone interview (Fig. 1). Characteristics of the study sample and nonresponders are shown in Table 1. Those not

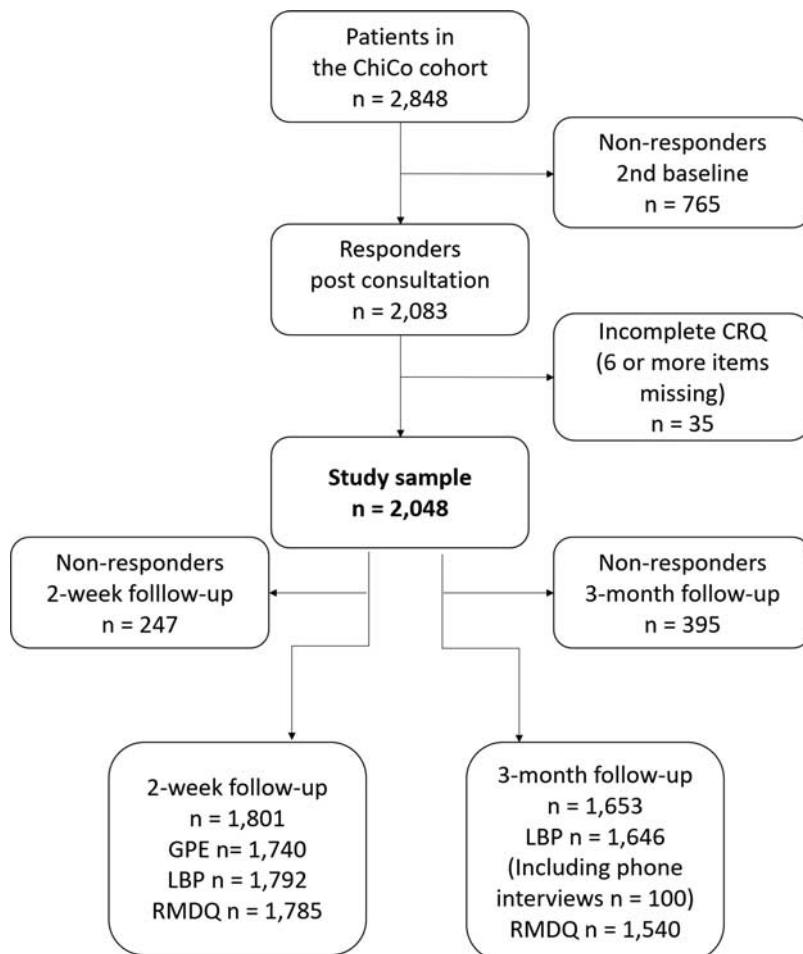


FIGURE 1. Study flow chart. CRQ indicates Consultation-based Reassurance Questionnaire; GPE, Global Perceived Effect; LBP, low back pain; RMDQ, Roland-Morris Disability Questionnaire.

TABLE 1. Patient Characteristics

| | Nonresponders at Second Baseline or Incomplete CRQ* (N = 800) | Study Sample (N = 2048) | 3-months Responders (N = 1653) | 3-month Nonresponders (N = 395) |
|--|---|-------------------------|--------------------------------|---------------------------------|
| Age, mean (SD) | 41 (13) | 46 (13) | 47 (13) | 41 (13) |
| Sex: female (%) | 33 | 44 | 43 | 47 |
| Longest education (%) | | | | |
| No qualification | | 15 | 14 | 19 |
| Vocational education | NA | 29 | 29 | 27 |
| Short further education 2-3 y | | 12 | 13 | 11 |
| Education 3+ y | | 38 | 39 | 37 |
| Other | | 4 | 4 | 3 |
| Missing | | 2 | 1 | 3 |
| LBP intensity (0-10), median (IQR) | 7 (5-8) | 7 (6-8) | 7 (5-8) | 7 (6-8) |
| Missing (%) | 2 | 2 | 2 | 3 |
| Duration of current LBP episode (%) | | | | |
| < 1 wk | 48 | 46 | 46 | 47 |
| 1-4 wk | 25 | 23 | 24 | 19 |
| 1-3 mo | 10 | 12 | 12 | 14 |
| 3-12 mo | 7 | 7 | 7 | 8 |
| > 12 mo | 10 | 10 | 10 | 11 |
| Missing | 1 | 1 | 1 | 1 |
| Previous chiropractic care for LBP (yes) (%) | NA | 49 | 50 | 44 |
| Missing | | 10 | 11 | 8 |
| SBST risk group (%) | | | | |
| Low | 42 | 43 | 44 | 39 |
| Medium | 30 | 34 | 34 | 35 |
| High | 22 | 21 | 20 | 24 |
| Missing | 6 | 2 | 2 | 3 |
| Ability to control pain, median (IQR) | 5 (4-7) | 5 (4-7) | 5 (4-7) | 5 (3-7) |
| Missing (%) | 4 | 2 | 2 | 2 |
| Disability (RMDQ, 0-100), median (IQR) | 57 (35-74) | 60 (39-74) | 57 (39-74) | 61 (39-78) |
| Missing (%) | 8 | 2 | 1 | 4 |
| CRQ scores, median (IQR) | | | | |
| Data-gathering | NA | 14 (11-16) | 14 (11-16) | 14 (11-16) |
| Relationship-building | | 14 (12-16) | 14 (12-16) | 14 (11-16) |
| Generic reassurance | | 12 (8-15) | 12 (8-15) | 12 (9-15) |
| Cognitive reassurance | | 14 (11-16) | 14 (11-16) | 13 (11-15) |

*Incomplete CRQ: < 6 items completed.

CRQ indicates Consultation-based Reassurance questionnaire; IQR, interquartile range; LBP, low back pain; NA, not available; RMDQ, Roland-Morris Disability Questionnaire; SBST, STarT Back Screening Tool.

responding to the second part of the baseline questionnaire were more often men, but otherwise similar to the study population (Table 1). The most marked difference between responders and nonresponders to 3-month follow-up was nonresponders less often reporting previous chiropractic care (44%) than responders (50%). Otherwise, those not responding to questionnaires were similar to the study population (Table 1).

The CRQ

The scores on all 4 subscales of the CRQ showed a left-skewed distribution, indicating generally high levels of reassurance (Fig. 2). Generic reassurance had the lowest median value of 12 (interquartile range: 8 to 15), with the other CRQ domains having median score of 14 (Table 1).

Associations With 2 Weeks and 3 Months Outcomes

Associations between CRQ-subcales at baseline and pain and disability during follow-up were consistent but

weak (Table 2, Figs. 3, 4), and of similar magnitudes across the 4 subscales.

All 4 subscales of the CRQ were positively associated with GPE with relationship-building observed to have a somewhat weaker association with this outcome than the other subscales (Table 3, Fig. 5).

Moderation of the associations by SBST risk groups was uncertain (P ranging from 0.1 to 0.9) for the outcomes LBP intensity and disability, with associations tending to be weaker for the low-risk group in relation to disability than for the medium-risk and high-risk groups (Table S1, Supplemental Digital Content 1, <http://links.lww.com/CJP/A784>). For GPE, the interactions between SBST risk groups and CRQ domains were also weak and likely to be observed by chance ($P=0.3$ to 0.9). Observed interactions mostly, but not systematically, indicated weaker positive associations with GPE for the medium-risk and high-risk SBST groups than for patients in the low-risk group (Table S2, Supplemental Digital Content 2, <http://links.lww.com/CJP/A785>).

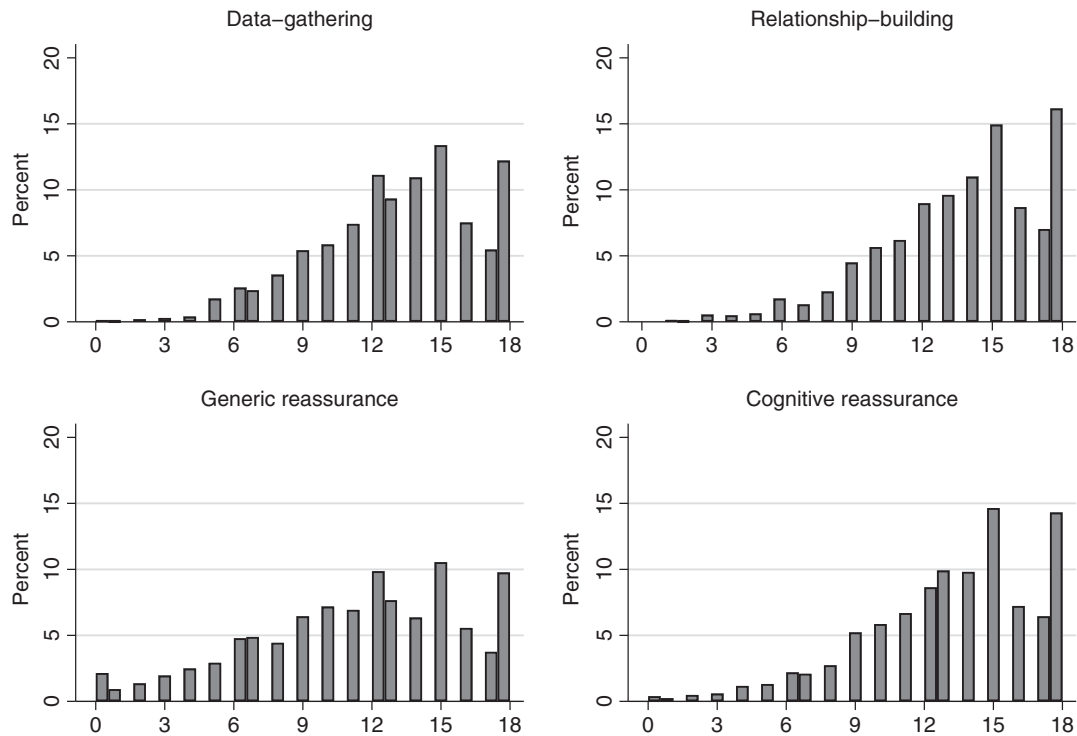


FIGURE 2. Distribution of scores on the 4 Consultation-based Reassurance Questionnaire subscales.

TABLE 2. Associations, β -coefficient (95% CI), Between CRQ-subcales and Outcomes in Longitudinal Models

| | β (95% CI) | |
|-----------------------------|------------------------|---------------------------|
| | LBP Intensity (0-10) | Disability (0-100) |
| Data-gathering | 0.02 (0.00-0.05) | -0.15 (-0.43 to 0.13) |
| 2 wk | -2.29 (-2.77 to -1.83) | -17.61 (-22.28 to -12.93) |
| 3 mo | -3.52 (-4.00 to -3.04) | -31.72 (-36.58 to -26.86) |
| Data-gathering×time* | | |
| 2 wk | -0.05 (-0.09 to -0.02) | -0.56 (-0.90 to -0.22) |
| 3 mo | -0.06 (-0.10 to -0.03) | -0.29 (-0.65 to 0.07) |
| P | 0.0005† | 0.006† |
| Relationship-building | 0.04 (0.01-0.07) | -0.07 (-0.37 to 0.23) |
| 2 wk | -2.15 (-2.67 to -1.63) | -14.38 (-19.55 to -0.40) |
| 3 mo | -3.08 (-3.62 to -2.55) | -27.93 (-33.32 to -22.54) |
| Relationship-building×time* | | |
| 2 wk | -0.06 (-0.10 to -0.02) | -0.77 (-1.13 to -0.40) |
| 3 mo | -0.09 (-0.13 to -0.06) | -0.55 (-0.93 to -0.17) |
| P | <0.0001† | 0.0001† |
| Generic reassurance | 0.04 (0.02-0.06) | -0.06 (-0.28 to 0.15) |
| 2 wk | -2.16 (-2.48 to -1.84) | -15.13 (-18.34 to -11.93) |
| 3 mo | -3.28 (-3.61 to -2.94) | -28.17 (-31.52 to -24.83) |
| Generic reassurance×time* | | |
| 2 wk | -0.07 (-0.10 to -0.04) | -0.86 (-1.12 to -0.60) |
| 3 mo | -0.10 (-0.12 to -0.07) | -0.65 (-0.92 to -0.37) |
| P | <0.0001† | <0.0001† |
| Cognitive reassurance | 0.03 (0.00-0.05) | -0.23 (-0.49 to 0.04) |
| 2 wk | -2.37 (-2.82 to -1.92) | -17.26 (-21.71 to -12.81) |
| 3 mo | -3.42 (-3.88 to -2.96) | -31.25 (-35.88 to -26.62) |
| Cognitive reassurance×time* | | |
| 2 wk | -0.05 (-0.08 to -0.01) | -0.58 (-0.90 to -0.26) |
| 3 mo | -0.07 (-0.10 to -0.04) | -0.32 (-0.66 to 0.01) |
| P | 0.0001† | 0.002† |

*The interaction terms estimate the additional weekly change in LBP intensity and disability for each increment (1 to 18 points) on the CRQ-subcales.

†P-values for interactions between CRQ-subcales and time.

CI indicates confidence interval; CRQ, Consultation-based Reassurance Questionnaire; LBP, low back pain.

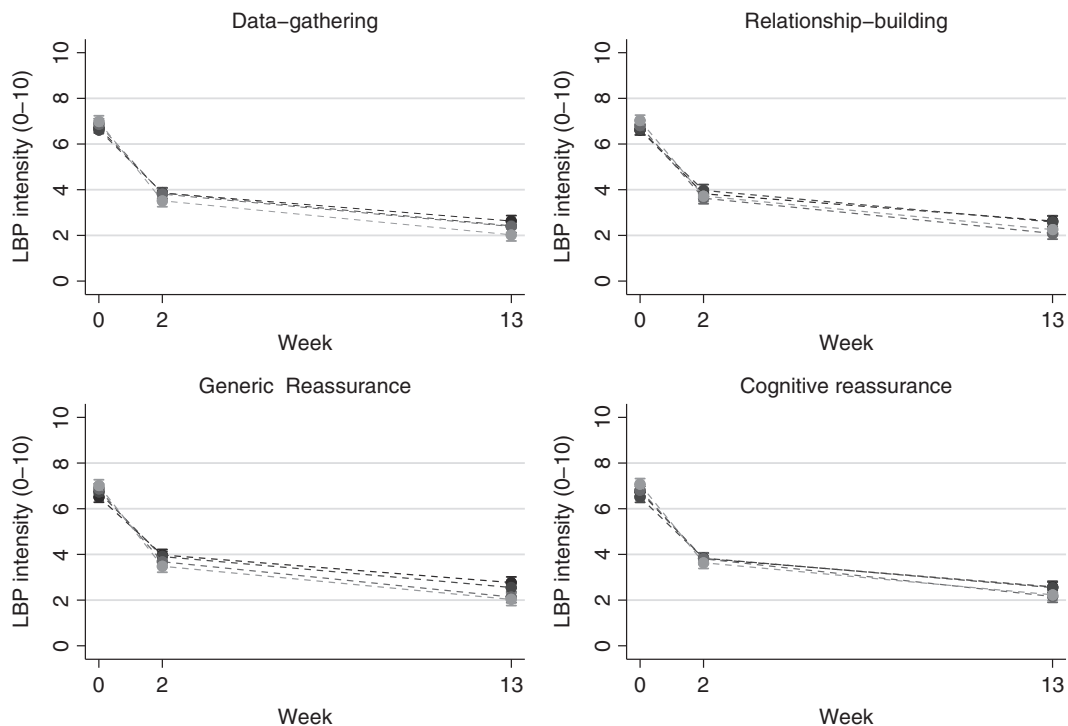


FIGURE 3. Predicted low back pain (LBP) intensity over time in quartiles of scores on the Consultation-based Reassurance Questionnaire.

DISCUSSION

This study is the largest to date investigating reassurance levels in LBP patients and the first to collect data within few days after the consultation that patients were

asked to report on. Levels of reassurance were generally high but varied across the full span of the scale, and levels of generic reassurance were slightly lower than for other sub-scales. The associations observed between the CRQ and

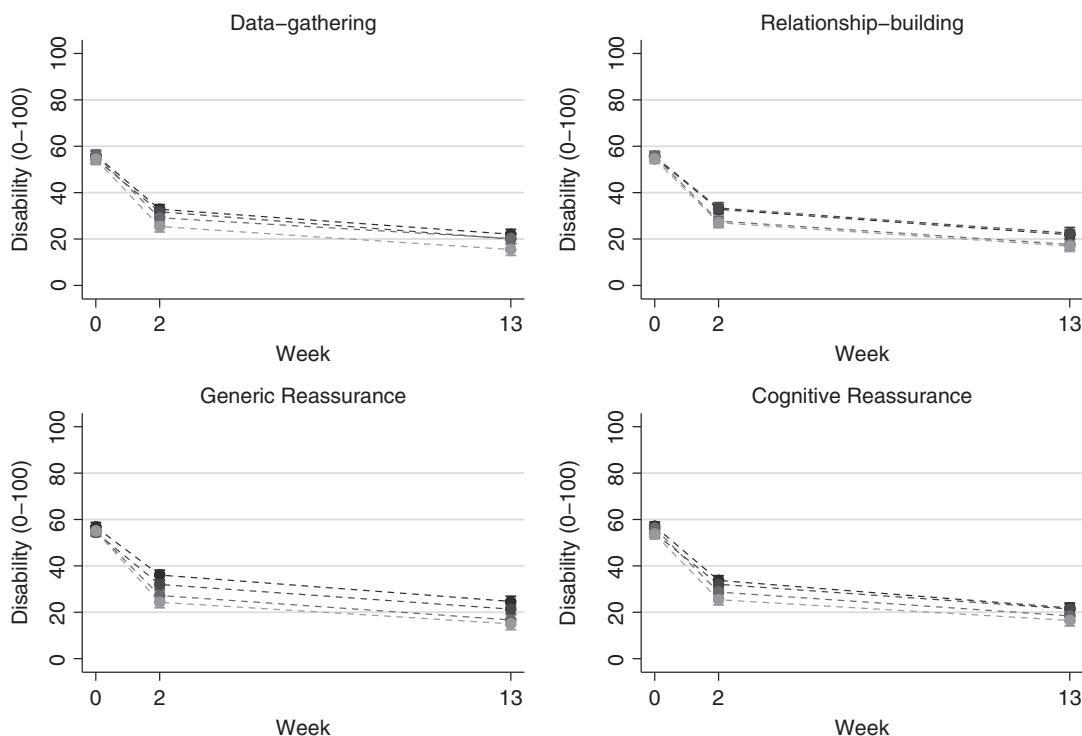


FIGURE 4. Predicted disability over time in quartiles of scores on the Consultation-based Reassurance Questionnaire.

TABLE 3. Associations, OR (95% CI), Between the CRQ-subcales and GPE at 2-week follow-up

| | Improved (N = 1740), OR (95% CI) | P |
|----------------------------|-------------------------------------|---------|
| Data-gathering | | 0.002 |
| First quartile (reference) | — | |
| Second quartile | 1.24 (0.95-1.64) | |
| Third quartile | 1.21 (0.89-1.64) | |
| Fourth quartile | 1.93 (1.39-2.71) | |
| Relationship-building | | 0.0009 |
| First quartile (reference) | — | |
| Second quartile | 1.07 (0.80-1.44) | |
| Third quartile | 1.69 (1.26-2.28) | |
| Fourth quartile | 1.53 (1.13-2.06) | |
| Generic reassurance | | <0.0001 |
| First quartile (reference) | — | |
| Second quartile | 1.17 (0.88-1.55) | |
| Third quartile | 1.66 (1.22-2.25) | |
| Fourth quartile | 2.17 (1.53-3.08) | |
| Cognitive reassurance | | 0.001 |
| First quartile (reference) | — | |
| Second quartile | 1.27 (0.95-1.69) | |
| Third quartile | 1.46 (1.08-1.97) | |
| Fourth quartile | 1.90 (1.37-2.63) | |

ORs are increased odds per increment (1 to 18 points) on the CRQ-subcales.
 CI indicates confidence interval; CRQ, Consultation-based Reassurance Questionnaire; GPE, Global Perceived Effect; OR, odds ratio.

LBP intensity and disability were positive but weak, whereas the association with GPE at 2 weeks follow-up seemed to be of a clinically relevant magnitude. It is possible that stronger relationships between reassurance and patient outcomes

would be present in samples with more people reporting lower levels of reassurance than in the present study.

In this study, cognitive reassurance was weakly associated with a reduction in LBP intensity at 2 weeks and 3 months follow-up. This is contrary to the study by Holt et al¹⁵ that found higher levels of cognitive reassurance associated with increased pain at 3 months follow-up. This difference might be due to some methodological differences between the studies. In this study, participants completed the CRQ within 48 hours postconsultation, whereas in the study by Holt and colleagues participants were included up to 1 month after the consultation which increased the risk of recall bias. Patients with LBP often experience a change in symptoms within 1 month and the status of back pain at the point of responding to the CRQ potentially affect their recall of the consultation.²⁷ The study by Holt and colleagues found that generic reassurance was the subscale most strongly associated with disability, which we also observed although differences between subscales were minor.

The observed association between the CRQ and GPE was of a magnitude that seems clinically relevant after controlling for measured confounders. The odds of being improved were about twice as large for the highest quartile of CRQ scores as compared with the lowest quartile. Given that the GPE reflects what individual patients value when it comes to their perception of the changes they experienced, this seems substantial.²⁸ The outcomes pain, disability, and GPE were chosen as these are considered core outcomes in LBP,²⁹ and for the study to be comparable to previous studies measuring reassurance by the CRQ. For future studies it would be relevant to address relationships between levels of perceived reassurance and other outcomes that may be more closely related to this such as illness beliefs.

Patients' psychological risk profile did not moderate the associations between CRQ-subcales and outcomes to a

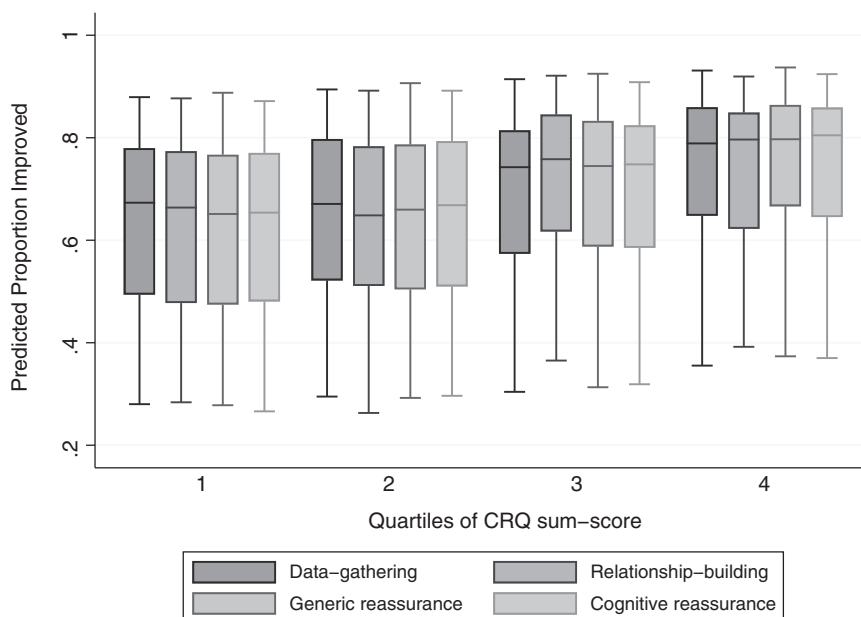


FIGURE 5. Associations between the CRQ-subcales and Improvement on Global Perceived Effect. Predicted proportions of patients that were improved at 2-week follow-up in quartiles of total CRQ sum-scores. CRQ indicates Consultation-based Reassurance Questionnaire.

notable degree. This means that associations were also present in patients with low-risk profiles, and the potential importance of reassuring communication should not be underestimated in patients with noncomplex LBP. This finding is in line with earlier findings that psychological risk profiles did not moderate associations between CRQ and pain or disability.¹⁵ However, in that relatively small study (n = 142) generic reassurance appeared to affect depression positively in people with low-risk profiles, but negatively in people with a high-risk profile. That finding needs to be confirmed in future studies.

This study adds important information to the limited knowledge about CRQ in patients with LBP due to the large study sample, and a design in which participants completed the CRQ shortly after the consultation which reduced the risk of recall bias. An observational study with wide inclusion criteria allowed us to investigate reassurance in unselected patients after routine consultations with no special training of clinicians. However, this meant that although most study participants had recent onset of LBP, the study population was heterogenous regarding symptom duration, which was handled by adjusting analyses for episode duration and previous care. Defining a true inception cohort is difficult in LBP as it is a condition that often starts early in life and is recurrent in nature.¹⁹ The analyses were adjusted for a number of potential confounders recognizing that clinicians may provide different levels of reassurance related to each patient's likely outcome, but the study design does not provide evidence of a causal relationship.

Very few cases were excluded because of incomplete responses to the CRQ and the response rate at follow-up was fairly high for the study sample. Still, 800/2848 (28%) enrolled in the ChiCo cohort did not respond to the second baseline questionnaire that included the CRQ. This may impact on the results, but based on the profile of the dropouts, there are no obvious reasons to suspect this. Clearly, it is a strength of this study that a validated instrument was used to measure the patients' perceived reassurance level. The setting of chiropractic care is not representative of all health care settings managing LBP, and future studies should investigate levels of reassurance in different settings and populations. If low levels of reassurance are observed, and the associations observed in this study reflect a causal relationship, improved outcomes might be achieved by relatively simple means. This is noteworthy because associations were sustained up to 3 months follow-up, and it might be speculated that successful reassurance has the potential to profoundly affect beliefs or behaviors. However, so far thoroughly designed interventions to achieve this have not proven effective.^{17,18}

CONCLUSIONS

Levels of reassurance measured by the CRQ in chiropractic consultations were positively associated with outcomes, and this was found across patient risk profiles. The clinical implications are still unclear, but even the weak observed associations would be worthwhile if these can be obtained simply by improved communication.

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REFERENCES

1. GBD 2015 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet*. 2016;388:1545-1602.
2. Hartvigsen J, Hancock MJ, Kongsted A, et al. What low back pain is and why we need to pay attention. *Lancet*. 2018;391:2356-2367.
3. Wong JJ, Cote P, Sutton DA, et al. Clinical practice guidelines for the noninvasive management of low back pain: a systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration. *Eur J Pain*. 2017;21:201-216.
4. Koes BW, van Tulder M, Lin CW, et al. An updated overview of clinical guidelines for the management of non-specific low back pain in primary care. *Eur Spine J*. 2010;19:2075-2094.
5. Foster NE, Anema JR, Cherkin D, et al. Prevention and treatment of low back pain: evidence, challenges, and promising directions. *Lancet*. 2018;391:2368-2383.
6. Traeger A, Buchbinder R, Harris I, et al. Diagnosis and management of low-back pain in primary care. *CMAJ*. 2017;189:E1386-E1395.
7. Oliveira CB, Maher CG, Pinto RZ, et al. Clinical practice guidelines for the management of non-specific low back pain in primary care: an updated overview. *Eur Spine J*. 2018;27:2791-2803.
8. Linton SJ, McCracken LM, Vlaeyen JW. Reassurance: help or hinder in the treatment of pain. *Pain*. 2008;134:5-8.
9. Giroldi E, Veldhuijzen W, Mannaerts A, et al. "Doctor, please tell me it's nothing serious": an exploration of patients' worrying and reassuring cognitions using stimulated recall interviews. *BMC Fam Pract*. 2014;15:73.
10. Holt N, Pincus T, Vogel S. Reassurance during low back pain consultations with GPs: a qualitative study. *Br J Gen Pract*. 2015;65:e692-e701.
11. Coia P, Morley S. Medical reassurance and patients' responses. *J Psychosom Res*. 1998;45:377-386.
12. Traeger AC, O'Hagan ET, Cashin A, et al. Reassurance for patients with non-specific conditions—a user's guide. *Braz J Phys Ther*. 2017;21:1-6.
13. Holt N, Pincus T. Developing and testing a measure of consultation-based reassurance for people with low back pain in primary care: a cross-sectional study. *BMC Musculoskelet Disord*. 2016;17:277.
14. Ben Ami N, Pincus T. Using the Consultation-based Reassurance Questionnaire to assess reassurance skills among physiotherapy students: reliability and responsiveness. *Physiother Theory Pract*. 2020:1-7. doi: 10.1080/09593985.2020.1812140
15. Holt N, Mansell G, Hill JC, et al. Testing a model of consultation-based reassurance and back pain outcomes with psychological risk as moderator: a prospective cohort study. *Clin J Pain*. 2018;34:339-348.
16. Kongsted A, Christensen MR, Ingersen KK, et al. Feasibility of the Consultation-based Reassurance Questionnaire in Danish chiropractic practice. *Chiropr Man Therap*. 2018;26:27.
17. Darlow B, Stanley J, Dean S, et al. The Fear Reduction Exercised Early (FREE) approach to management of low back pain in general practice: a pragmatic cluster-randomised controlled trial. *PLoS Med*. 2019;16:e1002897.
18. Traeger AC, Lee H, Hubscher M, et al. Effect of intensive patient education vs placebo patient education on outcomes in patients with acute low back pain: a randomized clinical trial. *JAMA Neurol*. 2019;76:161-169.
19. Kongsted A, Nielsen OL, Christensen HW, et al. The Danish Chiropractic Low Back Pain Cohort (ChiCo): description and summary of an available data source for research collaborations. *Clin Epidemiol*. 2020;12:1015-1027.
20. Provinciali L, Baroni M, Illuminati L, et al. Multimodal treatment to prevent the late whiplash syndrome. *Scand J Rehabil Med*. 1996;28:105-111.
21. Bolton JE, Wilkinson RC. Responsiveness of pain scales: a comparison of three pain intensity measures in chiropractic patients. *J Manipulative Physiol Ther*. 1998;21:1-7.
22. Linton SJ, Hallden K. Can we screen for problematic back pain? A screening questionnaire for predicting outcome in acute and subacute back pain. *Clin J Pain*. 1998;14:209-215.

23. Roland M, Fairbank J. The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. *Spine (Phila Pa 1976)*. 2000;25:3115–3124.
24. Kent P, Lauridsen HH. Managing missing scores on the Roland Morris Disability Questionnaire. *Spine (Phila Pa 1976)*. 2011;36:1878–1884.
25. Hill JC, Dunn KM, Lewis M, et al. A primary care back pain screening tool: identifying patient subgroups for initial treatment. *Arthritis Rheum*. 2008;59:632–641.
26. Kamper SJ, Ostelo RW, Knol DL, et al. Global perceived effect scales provided reliable assessments of health transition in people with musculoskeletal disorders, but ratings are strongly influenced by current status. *J Clin Epidemiol*. 2010;63:760.e1–766.e1.
27. Kongsted A, Kent P, Axen I, et al. What have we learned from ten years of trajectory research in low back pain? *BMC Musculoskelet Disord*. 2016;17:220.
28. Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain*. 2005;113:9–19.
29. Chiarotto A, Boers M, Deyo RA, et al. Core outcome measurement instruments for clinical trials in nonspecific low back pain. *Pain*. 2018;159:481–495.