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Feasibility and potential effectiveness of a primary care consultation tool: a pilot controlled trial

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Abstract

Background: The Primary Care Functioning Consultation Tool (PCFCT) supports the integration of different aspects of health related functioning for patients with multimorbidity in disease management programs.

Aim: To assess feasibility, satisfaction, and potential effectiveness of the PCFCT on functioning, self-efficacy, illness perceptions, and disease performance indicators in daily general practice.

Design and setting: Pilot non-randomized controlled trial in Dutch general practices

Method: Patients with multimorbidity were allocated to the intervention group (consultations with the practice nurse using the consultation tool) or to the control group (regular consultations). Feasibility was assessed by recruitment, retention, and identified patients at baseline and 3 months. After 3 months, satisfaction of patients and nurses was measured. Potential treatment effects were assessed using the Primary Care Functioning Scale, Self-efficacy Questionnaire, Brief Illness Perception Questionnaire, and disease-related outcomes.

Results: Sixty-five patients were included (31 intervention, 34 control). Both patients and practice nurses reported high satisfaction and acceptability. Nineteen control patients (59%) and 24 intervention patients (80%) completed all questionnaires at baseline and 3 months. Between-group differences were not statistically significant, however intervention patients showed small exploratory differences towards better functioning, higher self-efficacy, and more adaptive illness perceptions. Missing data ranged from 25% to >90% across disease performance indicators, precluding reliable comparisons.

Conclusion: The PCFCT is feasible, acceptable, and can be embedded within existing chronic disease management, with the potential to improve patient outcomes.

Keywords: multimorbidity; general practice; patient functioning; consultation tool; feasibility; non-randomized controlled trial

How this fits in

Patients with multimorbidity often experience impaired functioning, yet structured attention to functioning is not routinely embedded in consultations in general practice. This pilot trial suggests that a structured consultation tool based on functioning is feasible, acceptable, and has the potential to be integrated into routine chronic disease management. It may help clinicians better to address patients' functional limitations and priorities, supporting more personalised care in primary health care.

Introduction

In the Netherlands, most patients with chronic conditions in general practice are treated in structured chronic care care programs (ketenzorgprogramma's). These programs cover the most prevalent chronic diseases—such as type 2 diabetes, cardiovascular risk management, and COPD—and provide protocolized, guideline-based follow-up that is predominantly delivered by practice nurses, under the supervision of the general practitioner. However, many patients have multimorbidity (1-4), which is associated with reduced daily functioning, lower wellbeing, and challenges in self-care, for instance engaging in activities promoting physical and psychological health and managing the impact of the illness on physical, psychological and social functioning. (5-13)

Current guidelines and disease management programs insufficiently address the impact of multimorbidity on daily functioning, and healthcare professionals are not well equipped to assess and register functioning in a structured way. (14-16)

In order to support nurses and general practitioners (GPs) to address a more structured attention to functioning, the Primary Care Functioning Scale (PCFS) was developed. (17)

The PCFS is fully based on the International Classification of Functioning, Disability and Health (ICF), assesses multiple domains of functioning and has demonstrated its validity and reliability as a patient-reported outcome measure. (17-19)

The PCFS was translated into a consultation tool (Primary Care Functioning Consultation Tool, PCFCT) in order to make functioning a more structured part of the consultation. (20)

The consultation tool consists of an automatically processed personalized feedback report that summarizes and visualizes the main results of a patient's filled in web-based version of the PCFS, (see figure 1 appendix), which can be used by the patient and the practice nurse for discussion embedded in their regular consultations for the chronic disease. The PCFCT therefore consists of both the personalized feedback report and the structured discussion of functioning during the consultation. With the consultion tool, patients and practices nurses can focus on current problems in functioning, needs, and preferences to change or help to set achievable goals with defined actions.

The consultation tool was considered a promising consultation tool which could be applicable in existing chronic disease management programs in general practice in the Netherlands. (20) To study the feasibility and test potential effectiveness of the use of the

consultation tool in daily practice we conducted a pilot non-randomized controlled trial (non-RCT).

Feasibility such as recruitment, retention rates, and acceptability of the intervention among practice nurses and patients was assessed. Also possible effectiveness of the consultation tool was tested by assessing its impact on patient-reported outcomes such as health-related functioning, self-efficacy, and illness perceptions. This study is necessary for refining the trial design, optimizing measurement procedures, and ensuring the feasibility of a future large-scale RCT evaluating the consultation tool in primary care settings. (21-23)

Methods

Setting and participants

We developed a pilot non-RCT for patients with chronic morbidity in the general practice who participate in chronic disease management programs.

The study was performed within a Dutch Practice-Based Research Network (Radboudumc Academisch Huisartsennetwerk), which has longstanding experience in monitoring chronic illness and was involved in earlier development of the consultation tool. (17, 18, 20)

Ten different general practices from this network were approached and agreed to participate. General practices were alternatingly allocated to either the intervention group (regular scheduled consultation with the practice nurse using the consultation tool) or to the control group (regular control consultation with the practice nurse).

Practice nurses included five consecutive patients aged ≥65 years with diabetes mellitus and at least one additional chronic condition (CVD or COPD/asthma). Patients had to be able to complete online questionnaires. Patients receiving palliative care, with severe psychiatric disorders, or insufficient Dutch language skills were excluded. All participants provided written informed consent. Ethical approval was not required (Medical Research Ethics Committee Arnhem/Nijmegen, 2020-6747).

Procedure:

All patients were already scheduled for consultation by the practice nurse and completed the PCFS, the General Self-Efficacy Scale (GSES), and the Brief Illness Perception Questionnaire (B-IPQ) at baseline and after 3 months. After informed consent was received

patients in both groups received an email request to fill in the online questionnaires two weeks prior to their regular scheduled consultation with their practice nurse. In case of no response, the patient received two reminders by email (each reminder after 5 days of not responding).

After completing the PCFS, patients directly received an automatically generated online feedback report summarizing their functioning. In the intervention group, practice nurses were instructed how to use this report during consultations to discuss functioning, identify priorities, and support goal setting. In the control group, practice nurses had access to the report but were instructed not to initiate discussion.

Consultations lasted 30 minutes in both groups, in accordance with the regularly scheduled time. After 3 months patients and practice nurses were interviewed about their experiences and satisfaction with the consultation tool. Practice nurses participated in brief structured evaluation interviews after 3 months to explore feasibility, satisfaction, and experiences with integrating the consultation tool into routine care.

Outcome measures

Feasibility was evaluated by the number of identified patients, recruitment, and trial retention. Acceptability was assessed using satisfaction ratings (5-point Likert-type scale) in both groups and through 15-minute quantitative interviews with practice nurses after 3 months. Potential treatment effects were measured by the PCFS, GSES, and the B-IPQ.

The PCFS consists of 52 ICF-related items corresponding to all ICF's components: body functions, activities and participation, environmental factors, and personal factors.

The PCFS sum score reflects overall functioning, with higher scores indicating worse functioning. (18) Patients' experiences with the PCFS and resulting actions were explored in telephone interviews after 3 months. Self-efficacy was assessed with the GSES, with higher scores indicating greater self-efficacy. (24) Illness perceptions were measured using the B-IPQ, which assesses key cognitive and emotional representations of illness across eight dimensions, with higher scores indicating stronger perceptions. (25) Patients' experiences with the PCFS and resulting actions were explored in quantitative telephone interviews after 3 months.

Disease-related outcomes (BMI, blood pressure, HbA1c, LDL, eGFR) were extracted from the patients' electronic medical healthcare record. Health care use (e.g. visits to GP,

physiotherapist, psychologist, homeopath, medical specialist, etc.) was assessed by questionnaire after 3 months. Baseline characteristics, such as gender, age, marital status, level of education, occupation, morbidities, prescribed drugs, and self-rated physical health, mental health and quality of life during the past month, were derived from the PCFS questionnaire.

Statistical analysis

Descriptive statistics were used to summarise feasibility outcomes, including recruitment and retention. Continuous variables were presented as mean (SD) or median (IQR), and categorical variables as frequencies and percentages. Potential intervention effects were estimated using analysis of covariance with baseline values as covariates. To account for clustering of patients within practices, multilevel analyses with a random intercept model were performed. Analyses followed the intention-to-treat principle. Baseline differences were analysed using Student's t-tests or Mann–Whitney U tests for continuous variables and chi-squared or Fisher's exact tests for categorical variables. P-values <0.05 were considered statistically significant (two-sided). Analyses were performed using SPSS version 29 (IBM Corp., Armonk, NY).

Results

Patients' characteristics

After 3 months of recruitment, 10 general practices and 13 practice nurses had agreed to participate and the study was carried out from January 2021 to December 2021.
We found no difficulties with the identification and recruitment of eligible patients, and after 6 months, a total of 65 eligible patients (5 patients per practice nurse; 34 patients in the control group and 31 patients in the intervention group), had consented to participate. Differences in time needed to identify and recruit 5 eligible patients differed between practice nurses, ranging from 7 days (control group; mean 30 days) to 111 days (intervention group, mean 52 days). Sociodemographic and baseline characteristics are presented in table 1. As this was a low-risk consultation-based intervention integrated

within routine chronic disease management, no adverse events related to the intervention were reported.

TABLE 1: **Sociodemographic characteristics of the study participants (n=65)**

	Control (n = 34)	Intervention (n = 31)
Demographic characteristics		
Sex		
Male	21	18
Female	9	10
Mean age, years (SD)	73.1 (5.3)	70.9 (3.9)
Current marital status		
Married or in a relationship	24	22
Single, Divorced or Widowed	9	8
Level of education		
Low	4	9
Middle	13	6
High	12	8
Other	1	5
Occupation		
Working (remunerative, non-remunerative)	3	2
Non-working (retired, incapacity to work)	27	26
Morbidity		
Reported 0 (chronic) condition	1[2]	0
Reported 1 (chronic) condition	8	13
Reported 2 (chronic) conditions	8	8
Reported 3 or more (chronic) conditions	13	10
Number of prescribed drugs		
0-1	1	3
2-3	5	8
>3	24	17
Self-rated physical health during the past month		
Very good to good	12	16
Fair	12	8
Mediocre to poor	6	4
Self-rated mental health during the past month		
Very good to good	24	18
Fair	4	7
Mediocre to poor	2	3
Self-rated overall quality of life		
Very good to good	22	17
Fair	6	8
Mediocre to poor	2	3

[1]Level of education was categorized into low (no education and primary and lower secondary education), middle (upper secondary education), and high (pre-university, higher vocational training, and university). Missing values are not included in the percentage calculation. [2]Participant did not self-identify their conditions as chronic in the questionnaire

Trial retention, response rates and acceptability

In the control group 14 patients (41%) received one reminder by email to complete the questionnaires and 5 patients (15%) received a second reminder, 3 patients (9%) did not respond at all after the second reminder. In the intervention group 9 patients (29%) received one reminder by email to complete the questionnaires and 6 patients (19%) received a second reminder, 2 patients did not respond at all after the second reminder (6%). Nineteen patients from the control group (59%) and 24 patients from the intervention group (80%) completed all questionnaires at baseline and 3-month follow-up.

After 3 months, telephone interviews were conducted to evaluate patients' experiences with and satisfaction regarding the PCFS questionnaire, feedback report, and consultation tool. In the control group, 21 patients (62%) and in the intervention group 24 patients (77%) could be reached and agreed to participate in the interview. Information on reasons for non-response was limited, as some non-responders could not be reached for the evaluation interviews. In several cases, practice nurses reported that patients no longer attended consultations at the practice due to illness or external personal circumstances.

Results from the evaluation interviews showed that 14 patients (67%) in the control group and 23 patients (96%) in the intervention group were (very) satisfied with the online PCFS questionnaire and/or feedback report. Additional patient-reported experiences with the PCFS and consultation tool are summarized in Table 2.

TABLE 2: Patient-reported experiences per intervention group

Control group (PCFS, n = 21)	
Outcome	**n (%)**
Discussed feedback report with practice nurse	4 (19%)
Would have liked to discuss results and expected nurse to initiate discussion	6 (29%)
Forgot to mention / discuss the feedback report	6 (29%)
Feedback report stimulated healthier lifestyle goal	1 (5%)
Visited paramedic in past 3 months	9 (43%)
Would recommend using the tool in future health care settings	15 (75%)
Intervention group (PCFCT, n = 24)	
Outcome	**n (%)**
(Very) satisfied with the tool	22 (92%)
Tool helped gain more insight in own functioning	23 (96%)

Made goals because of the consultation tool	10 (42%)
Visited paramedic in past 3 months	6 (25%)
Would recommend using the tool in future health care settings	19 (79%)

After 3 months, all practice nurses were available for the evaluation interview (excluding one practice nurse experiencing problems with her email and availability for the study). Evaluation interviews with practice nurses suggested that the consultation tool was generally implemented as intended. Most practice nurses in the intervention group reported actively using the feedback report during consultations to discuss functioning and support goal setting with patients. In the control group, one practice nurse studied the PCFS and the feedback report (and reported she was satisfied with the consultation tool, the other practice nurses did not study the PCFS and feedback report. In the intervention group, most practice nurses were (very) satisfied with the consultation tool. Nearly all practice nurses would add the consultation tool to the existing care for patients with chronic diseases.

Estimates of potential treatment effects

Outcome measures were obtained from 60 patients. Outcome measures at baseline and after 3 months for both groups are summarized in table 3.

After 3 months, patients in the intervention group scored on average 1.5 points lower on the PCFS sum score compared to patients in the control group (mean difference = -1.5, 95% CI -3.2 to 0.1), indicating better functioning, although this difference was not significant (p=0.07). Similar non-significant differences were observed for bodily and mental functioning (-0.6, 95% CI -1.3 to 0.1) and activity and participation (-1.0, 95% CI -2.2 to 0.3) with consistently better functioning in the intervention group compared to the control group.

Self-efficacy was slightly higher in the intervention group after 3 months (0.7, 95% CI −2.3 to 3.8), although this difference was not statistically significant.

Differences between groups were small and non-significant across all B-IPQ items. However, patients in the intervention group scored slightly lower on consequences, timeline, personal control, identity, concern, and emotional representation, suggesting more adaptive illness perceptions. They scored somewhat higher on treatment control (1.4, 95% CI −0.02 to 2.7)

and coherence (0.6, 95% CI −1.4 to 2.6), reflecting greater perceived treatment efficacy and understanding of their condition.

TABLE 3. Effects of usual care and PCFCT after 3-month follow-up

	Control		Intervention		Differences between groups
	Means (SD)		Means (SD)		Means (95% CI)
	baseline	3-month follow up	baseline	3-month follow up	3-month follow up
PCFS (total functioning)[1]	38.1 (6.1) n = 30	39.7 (5.4) n = 19	39.1 (5.9) n = 30	38.4 (6) n = 24	-1.5 (-3.2 to 0.1)
PCFS (bodily and mental functioning)[1]	16.7 (2.8) n = 30	17.4 (2.3) n = 19	17.6 (2.3) n = 30	17.2 (2.7) n = 24	-0.6 (-1.3 to 0.1)
PCFS (activity and participation)[1]	21.4 (3.6) n = 30	22.4 (3.6) n = 19	21.5 (4.1) n = 30	21.2 (3.7) n = 24	-1 (-2.2 to 0.3)
Self-efficacy score[2]	23.4 (3.4) n = 31	22.7 (4.8) n = 20	21.5 (4.4) n = 30	22.9 (3.4) n = 25	0.7 (-2.3 to 3.8)
Brief IPQ item 1: consequences[3]	4.9 (2.7) n = 30	5.1 (2.4) n = 20	4.6 (2.7) n = 30	4.6 (2.8) n = 25	-0.5 (-2.0 – 0,9)
Brief IPQ item 2: timeline[3]	9 (1.8) n = 30	9.2 (1.7) n = 20	8.4 (2.4) n = 30	8.3 (2.3) n = 25	-0.8 (-2.0 – 0.4)
Brief IPQ item 3: personal control[3]	6.8 (1.6) n = 30	6.7 (1.3) n = 20	6.4 (2.3) n = 30	6.1 (2.4) n = 25	-0.6 (-2.1 – 1.0)
Brief IPQ item 4: treatment control[3]	7.2 (1.6) n = 30	5.8 (2.5) n = 20	6.7 (1.6) n = 30	7 (2.1) n = 25	1.4 (-0.02 – 2.7)
Brief IPQ item 5: identity for describing the condition and symptoms[3]	4.8 (2.7) n = 30	5.2 (2.2) n = 20	4.3 (2.7) n = 30	4.6 (2.5) n = 25	-0.6 (-2.1 – 0.8)
Brief IPQ item 6: concern and emotions[3]	4.7 (2.5) n = 30	5.3 (2.3) n = 20	4.6 (2.4) n = 30	4.5 (3) n = 25	-0.7 (-2.3 – 0.9)
Brief IPQ item 7: coherence[3]	7.4 (1.9) n = 30	6.8 (2.2) n = 20	6.8 (2.4) n = 30	7.2 (2.3) n = 25	0.6 (-1.4 – 2.6)
Brief IPQ item 8: concern and emotions[3]	3.7 (2.6) n = 30	4.1 (2.6) n = 20	3.5 (2.6) n = 30	3.6 (2.4) n = 25	-0.3 (-2.3 – 1.6)

[1] Higher scores reflect worse functioning
[2] Higher scores reflect better self-efficacy
[3] Higher scores reflect a stronger perception of the concerning item

For the disease outcome measures (BMI, blood pressure, HbA1c, LDL cholesterol, and eGFR), a substantial proportion of data was missing, i.e. not registered in the medical history record or not collected by the practice nurse, at baseline and follow up in both the intervention and control group (see Table 4). Missing data ranged from approximately 25% to over 90% across the different outcome variables, with the highest proportions of missing data being observed for LDL cholesterol and eGFR, particularly in the control group at baseline (90% and 73.3%, respectively). Because of the extent and uneven distribution of missing data, it was not possible to make valid between-group comparisons and calculate reliable effect sizes. Therefore, these measures were excluded from further inferential analyses.

TABLE 4 Disease outcome measures – Missing data in percentages per disease outcome (missing / total n)

Group	Measure	BMI	Blood pressure	HbA1C	LDL	eGFR
Control (n=30)	Baseline	40	33.3	63.3	90	73.3
Control (n=28)	Follow up	46.4	25	67.9	82.1	70
Intervention (n=31)	Baseline	67.7	32.3	64.5	64.5	67.7
Intervention (n=28)	Follow up	57.1	35.7	46.4	75	78.6

Discussion

Summary

In this pilot non-RCT we aimed to evaluate the feasibility, satisfaction and potential effectiveness of the consultation tool in existing routine chronic disease management in general practice. In total 65 patients with multimorbidity were included. Feasibility outcomes, including recruitment, retention, and user satisfaction as well as potential treatment effects, were assessed after 3 months.

Most practice nurses reported no major difficulties in identifying and recruiting eligible patients, although recruitment took longer in the intervention group, possibly due to the additional time and effort required to integrate the consultation tool into routine care. Most patients in the intervention group were satisfied, reporting increased insight into their functioning and support for goal setting during consultations, see Table 2. Practice nurses also considered the tool useful and feasible for integration into routine care.

Although the between-group differences were not statistically significant, the analyses demonstrated that patients in the intervention group showed exploratory differences toward better functioning, slightly higher self-efficacy, and more adaptive illness perceptions—particularly higher perceived treatment control and coherence. Disease outcome measures could not be analyzed due to extensive missing data.

Comparison with the literature

The findings of this pilot trial are in line with earlier research demonstrating that incorporating patient-reported outcome measures (PROMs) and functioning-based feedback can enhance patient engagement and communication in chronic disease management. In general, patients appreciate the systematic use of PROMs to discuss aspects of their health that extend beyond disease control, although implementing PROMs in routine primary care remains challenging. (26)

Similar findings have been reported in other settings. For example, nurse-led PROM-based interventions for patients with multimorbidity have been shown to be acceptable to both patients and professionals and to support reflection on health status. (27)

In addition, systems integrating patient-reported data into routine care have demonstrated improvements in patient-perceived quality of care and functioning. (26)

A Cochrane review further supports that routine use of PROMs can improve patient–clinician communication and awareness of quality of life. (28)

Compared with previous studies, the present pilot focused on integrating a functioning-based consultation tool into routine chronic disease management. In line with feasibility frameworks, we demonstrated high acceptability, good retention, and successful implementation within existing consultations. (23) Although no statistically significant effects were found, consistent trends toward better functioning, higher self-efficacy, and more adaptive illness perceptions were observed. These findings are in line with earlier PROM-based interventions and provide initial estimates for designing a larger randomized trial.

Strengths and limitations

A strength of this pilot RCT is the inclusion of a broad range of outcome measures alongside feasibility outcomes, including functioning, self-efficacy, illness perceptions, and disease-

related parameters. This allowed exploration of multiple aspects of health and the practicality of collecting these measures in routine primary care, providing valuable insights for the design of a definitive trial. The collection of disease-related outcomes revealed important methodological challenges. Clinical parameters were extracted from electronic health records without a standardized procedure, resulting in heterogeneous and incomplete datasets. Time constraints and variability in data collection contributed to substantial missing data, precluding reliable analyses. Future trials should use standardized and preferably automated data extraction methods to improve data quality and reduce burden on practice nurses. Another limitation is the relatively short follow-up period of 3 months, which may have been insufficient to detect longer-term effects on functioning, self-efficacy, illness perceptions, and clinical outcomes. A longer follow-up period should be considered in future studies. Also, the included population likely consisted of patients with relatively sufficient digital skills, which may limit generalizability. Future research should therefore explore how the PCFCT can also be implemented for patients with limited digital literacy, for example by offering assisted completion, paper-based versions, or integration during the consultation itself.

Implications for research and / or clinical practice

This pilot study demonstrates that the consultation tool is feasible, acceptable, and potentially effective and can be embedded within existing chronic disease management programs within Dutch general practice. By addressing functioning, needs, and goal setting alongside disease-specific indicators, the tool supports a more person-centred approach to managing multimorbidity. In clinical practice, it may help practice nurses tailor care to patients' functional limitations and personal priorities, thereby strengthening patient involvement and self-management.

For future research, these findings support the feasibility of a larger, adequately powered randomized controlled trial with longer follow-up to confirm effects on functioning, self-efficacy, and illness perceptions. Although the observed exploratory effect sizes were small and their clinical relevance remains uncertain, the direction and consistency of the findings provided sufficient preliminary signal to justify further evaluation of the PCFCT in a future adequately powered trial.

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Ethical approval

Ethical approval was not required (Medical Research Ethics Committee Arnhem/Nijmegen, 2020-6747)

Declaration of interests

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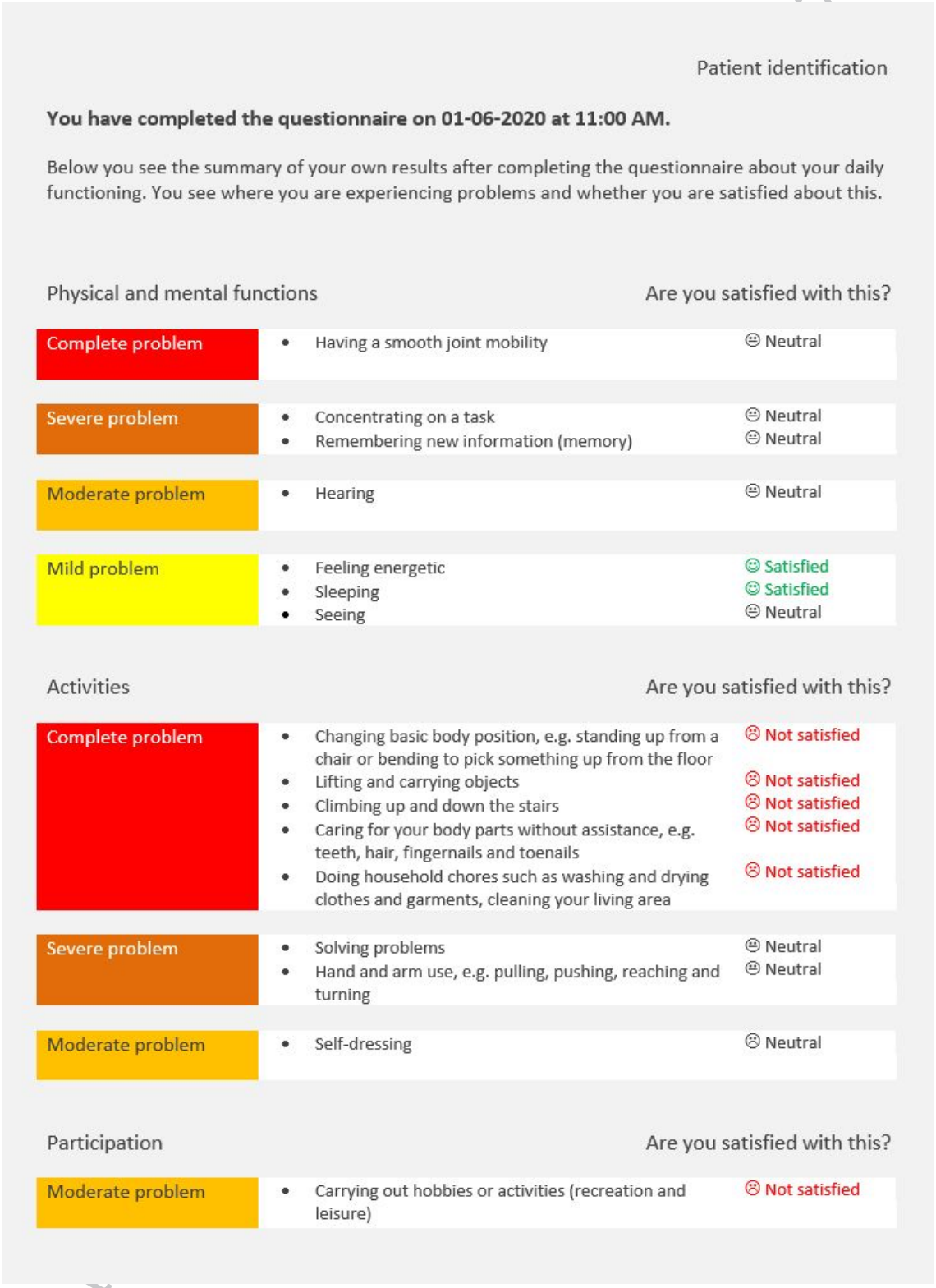
Figure 1 Personalized feedback report of the Primary Care Functioning Scale



Patient identification

You have completed the questionnaire on 01-06-2020 at 11:00 AM.

Below you see the summary of your own results after completing the questionnaire about your daily functioning. You see where you are experiencing problems and whether you are satisfied about this.

Physical and mental functions		Are you satisfied with this?
Complete problem	• Having a smooth joint mobility	😐 Neutral
Severe problem	• Concentrating on a task	😐 Neutral
	• Remembering new information (memory)	😐 Neutral
Moderate problem	• Hearing	😐 Neutral
Mild problem	• Feeling energetic	☺ Satisfied
	• Sleeping	☺ Satisfied
	• Seeing	😐 Neutral

Activities		Are you satisfied with this?
Complete problem	• Changing basic body position, e.g. standing up from a chair or bending to pick something up from the floor	☹ Not satisfied
	• Lifting and carrying objects	☹ Not satisfied
	• Climbing up and down the stairs	☹ Not satisfied
	• Caring for your body parts without assistance, e.g. teeth, hair, fingernails and toenails	☹ Not satisfied
	• Doing household chores such as washing and drying clothes and garments, cleaning your living area	☹ Not satisfied
Severe problem	• Solving problems	😐 Neutral
	• Hand and arm use, e.g. pulling, pushing, reaching and turning	😐 Neutral
Moderate problem	• Self-dressing	☹ Neutral

Participation		Are you satisfied with this?
Moderate problem	• Carrying out hobbies or activities (recreation and leisure)	☹ Not satisfied

Figure 2 Flow diagram of allocation patients