J Rehabil Med 2022; 54: jrm00309

ORIGINAL REPORT

EVALUATION OF ALLIED HEALTHCARE IN PATIENTS RECOVERING FROM COVID-19: STUDY PROTOCOL AND BASELINE DATA OF A NATIONAL PROSPECTIVE COHORT STUDY

Dutch Consortium Allied Healthcare COVID-19: Rob A. DE BIE, PT, PhD[1], Arie C. VERBURG, PT, MSc[2], Carla AGASI-IDENBURG, PhD[3], Edith H. C. CUP, OT, PhD[4], Carolien DEKKER, PT, PhD[1], Johanna M. VAN DONGEN, PhD[5], Edwin GELEIJN, PT[6], Marissa H. G. GERARDS, PT, MSc[1,7], Maud GRAFF, OT, PhD[2,4], Ron VAN HEERDE, PT, MSc[2], Hanneke KALF, MSc, PhD[4], Marly KAMMERER, OT, MSc[4], Renée A. KOOL, M[8], Anja DE KRUIF, MSc[9], Hinke M. KRUIZENGA, RD, PhD[10], Marike VAN DER LEEDEN, PT, PhD[6], Ton A. F. LENSSEN, PT, PhD[1,7], Willemijn M. MEIJER, PhD[11], Raymond OSTELO, PT, PhD[5,12], Amber RONTELTAP, PhD[3], Marike VAN DER SCHAAF, PT, PhD[6], Sonja VAN OERS, PhD[9], Marian A. E. DE VAN DER SCHUEREN, PhD[9,13], Anne I. SLOTEGRAAF, MSc[13], Cindy VEENHOF, PT, PhD[3,14], Thomas J. HOOGEBOOM, PT, PhD[2] and Philip J. VAN DER WEES, PT, PhD[2,4]

From the [1]CAPHRI School for Public Health and Primary Care, Faculty of Health, Medicine and Life Sciences, Maastricht University, Maastricht, [2]Radboud Institute for Health Sciences, IQ Healthcare, Radboud University Medical Center, Nijmegen, [3]Research Group Innovation of Movement Care, University of Applied Sciences Utrecht, Utrecht, [4]Donders Institute for Brain, Cognition and Behaviour, Department of Rehabilitation, Radboud University Medical Center, Nijmegen, [5]Department of Health Sciences, Faculty of Science, Vrije Universiteit Amsterdam, Amsterdam Movement Sciences Research Institute, [6]Department of Rehabilitation Medicine, Amsterdam Movement Sciences Research Institute, Amsterdam University Medical Center, Vrije Universiteit Amsterdam, Amsterdam, [7]Department of Physical Therapy, Maastricht University Medical Center, Maastricht, [8]The Lung Foundation Netherlands, Amersfoort, [9]Department of Nutrition, Dietetics and Lifestyle, School of Allied Health, HAN University of Applied, Sciences, Nijmegen, [10]Department of Nutrition & Dietetics, Amsterdam UMC, and Faculty of Sports and Nutrition, Amsterdam University of Applied Sciences, Amsterdam, [11]Netherlands Institute for Health Services Research, Nivel, Utrecht, [12]Department of Epidemiology Mobility Care, University of Applied Epidemiology and Data Science, Amsterdam UMC, Location VUmc, Amsterdam, [13]Division of Human Nutrition and Health, Division of Human Nutrition and Health, Wageningen University & Research, Wageningen, [14]Department of Rehabilitation, Physical Therapy Science and Sport, Brain Center, University Medical Center Utrecht, Utrecht University, The Netherlands

Objective: **To report the study protocol and baseline characteristics of a prospective cohort study to evaluate longitudinal recovery trajectories of patients recovering from COVID-19 who have visited a primary care allied health professional.**

Design: **Report of the protocol and baseline characteristics for a prospective cohort study with a mixed-methods approach.**

Patients: **Patients recovering from COVID-19 treated by primary care dietitians, exercise therapists, occupational therapists, physical therapists and/or speech and language therapists in the Netherlands.**

Methods: **The prospective study will measure primary outcome domains: participation, health-related quality of life, fatigue, physical functioning, and costs, at baseline, 3, 6, 9 and 12 months. Interviews, on the patients' experiences with allied healthcare, will be held with a subsample of patients and allied health professionals.**

Results: **The cohort comprises 1,451 patients (57% female, mean age 49 (standard deviation 13) years). Preliminary results for the study cohort show that 974 (67%) of the participants reported mild/moderate severity symptoms during the infection period and patients reported severe restrictions in activities of daily living compared with previous research in other patient populations. Both quantitative and qualitative, will provide insight into the recovery of patients who are treated by allied health professionals.**

Conclusion: **In conclusion, this will be the first comprehensive study to longitudinally evaluate the recovery trajectories and related costs of patients recovering from COVID-19 who are treated by allied health professionals in the Netherlands. This study will provide evidence for the optimal strategy to treat patients recovering from COVID-19 infection, including which patients benefit, and to what extent, from treatment, and which factors might impact their recovery course over time. The preliminary results of this study demonstrated the severity of restrictions and complaints at the start of therapy are substantial.**

LAY ABSTRACT

This paper presents the protocol for a prospective study of patients recovering from COVID-19 who are treated by allied health professionals in Dutch primary care. In the forthcoming study, a total of 1,451 patients will be asked to complete questionnaires regarding their social participation in daily life, health-related quality of life, fatigue, physical functioning, and healthcare and societal costs at baseline, 3, 6, 9 (costs only) and 12 months. Furthermore, the allied health professionals will answer questions at the start and end of treatments. This report presents baseline characteristics for the study cohort. Initial findings indicate that patients in the current cohort report severe restrictions in activities of daily living compared with previous studies of other patient populations. This report also describes the protocol of the prospective study, which aims to longitudinally evaluate the recovery trajectories and related costs of patients recovering from COVID-19.

Key words: COVID-19; allied healthcare; rehabilitation; primary care.

Accepted 17 May 2022; Epub ahead of print 23 June 2022

J Rehabil Med 2022; 54: jrm00309

DOI: 10.2340/jrm.v54.2506

Correspondence address: Arie C. Verburg Dutch Consortium Allied Healthcare COVID-19, Radboud University Medical Center, 160 IQ Healthcare PO Box 9101, 6500 HB Nijmegen, The Netherlands. E-mail: koen.verburg@radboudumc.nl

INTRODUCTION

An estimated 32–57% of patients recovering from a COVID-19 infection experience severe problems in daily functioning and participation, which may persist in the long term (1, 2). Long-term effects of COVID-19, referred to as "post-COVID-19 syndrome" or "long COVID", can be defined as signs and symptoms that develop during or after a COVID-19 infection, which continue for more than 12 weeks and are not explained by an alternative diagnosis (3). Currently, a wide range of symptoms have been reported, with limitations in physical, nutritional, cognitive and mental functioning (including fatigue) (4–8). Allied health professionals may play an important role in the recovery of patients with COVID-19 who experience limitations in daily functioning and participation.

To address the needs of patients and the allied health professionals, mono- and multi-disciplinary best practice recommendations for managing COVID-19 care have been developed in the Netherlands (9–11) (see also Appendix I). Researchers, practitioners, and policymakers have developed and disseminated these recommendations in their respective fields. However, to our knowledge, no large-scale studies have evaluated mono- or multi-disciplinary allied healthcare in relation to the recovery trajectories of patients after a COVID-19 infection in primary care. Consequently, there is currently no evidence-base for use in allied healthcare regarding patients recovering from COVID-19.

The primary goal of this Preliminary paper is to describe the study protocol of a prospective cohort study that aims to evaluate the longitudinal recovery trajectories, including the experiences of participants, and associated costs, of patients who visit primary care allied health professionals for management of symptoms, activity limitations and/or participation restrictions related to COVID-19. Recovery will be assessed in terms of physical, nutritional, cognitive, and mental daily functioning of patients recovering from COVID-19. Knowledge of recovery trajectories, outcomes and costs will enable the adjustment of mono- and multi-disciplinary treatment guidelines for this patient group. A secondary goal of this preliminary paper is to report the baseline characteristics of patients included in the prospective cohort study.

METHODS

The overall aim of the prospective study is to evaluate the longitudinal recovery trajectories and related costs of patients who visit a primary care allied health professional for the management of severe symptoms and activity limitations and/or participation restrictions related to COVID-19. The study commenced in January 2021 and will be completed in December 2023.

The specific research questions of the prospective study are:

- To what extent do patients, who are recovering from a COVID-19 infection and have received allied healthcare, recover physical, nutritional, and mental functioning by 3, 6 and 12 months after the start of therapy?
- What changes in participation and health-related quality of life (HRQoL) are observed in patients after receiving allied healthcare?
- What are the overall treatment goals and types of interventions that allied healthcare employ in the management of patients recovering from COVID-19?
- What differences in recovery trajectories are observed between patients with COVID-19 receiving mono- vs multi-disciplinary allied healthcare?
- What factors influence patients' recovery patterns when receiving allied healthcare while recovering from COVID-19?
- What are the healthcare and societal costs of different mono- and multi-disciplinary allied healthcare trajectories, and how do they relate to the recovery of patients and their HRQoL at 3, 6, 9 and 12 months?
- What are the experiences of patients and allied health professionals with the recovery and allied health treatment after COVID-19?

Design and setting

This prospective cohort study collected quantitative data on usual care treatment trajectories since 29 March 2021 at the professional- and patient-level. Primary outcomes are assessed at baseline, and at 3, 6, 9 (only costs) and 12 months. Secondary outcome measures are assessed at baseline and at 6 months or at the end of treatment (except for 3 occupational therapy outcomes, which will also be collected at 12 months). The primary endpoint of the cohort study is set at 6 months. In this cohort study, all treatment trajectories offered by allied health professionals in daily practice are part of usual care and are preferably based on recommendations and guidelines published by the professional bodies of the

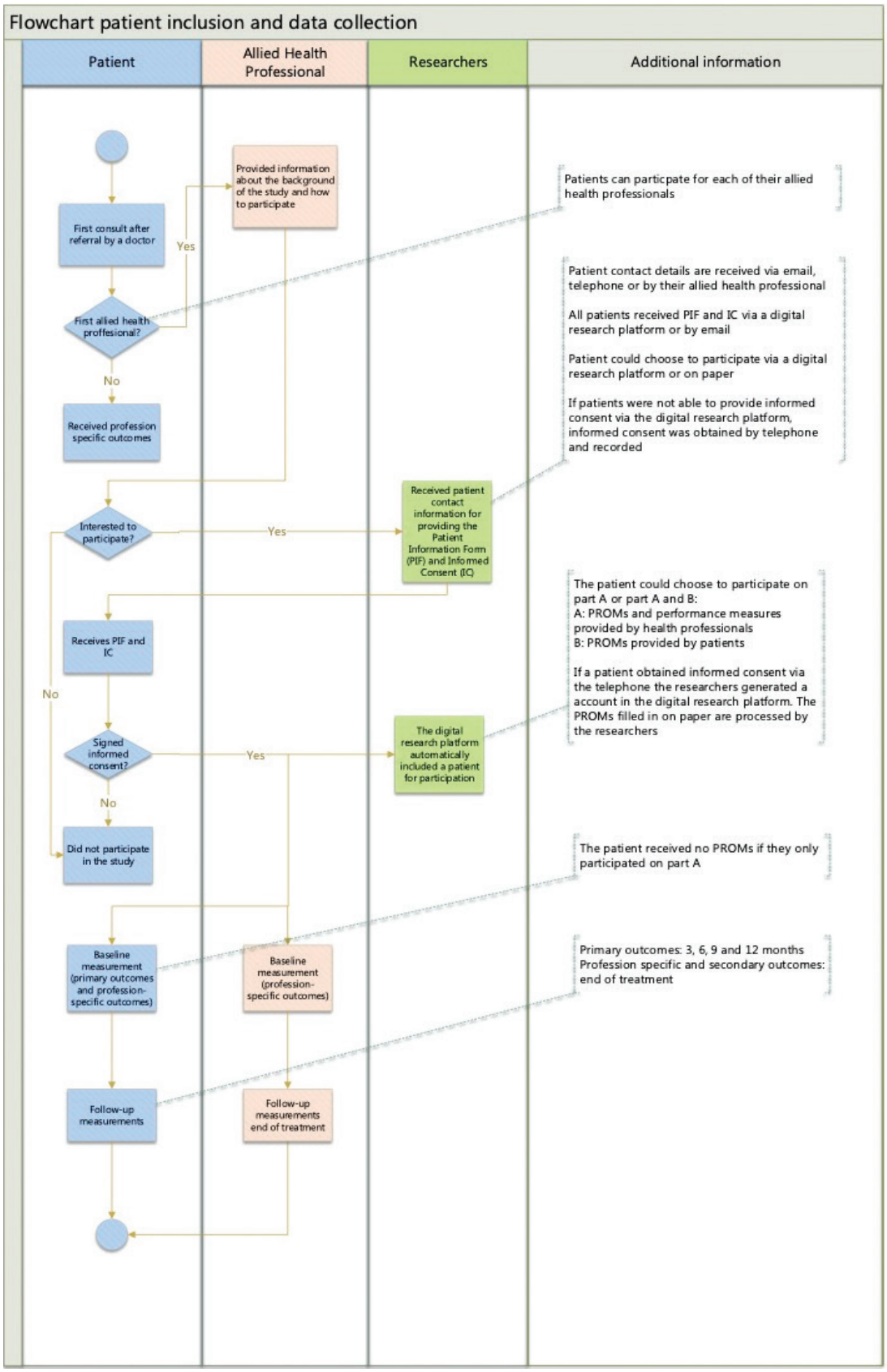

Fig. 1. Study flowchart patient inclusion and data collection.
PIF, Patient information form; IC, Informed consent; PROMs, Patient reported outcome measures

allied health professionals as available at the start of the research. Appendix I gives an overview of currently available treatment recommendations. An overview of the study flow is shown in Fig. 1.

Patient-level data of the quantitative cohort study will be combined with qualitative data on experiences of allied health professionals and patients in a mixed-methods study. Qualitative data will be collected by means of semi-structured interviews with purposefully sampled patients ($n = 30$) and 5 focus groups with allied health professionals ($n = 6–7$). To recruit patients to the qualitative studies, a subsample of patients will be purposively sampled to evaluate their experiences. The aim is to recruit a sample representing patients treated by different allied health professionals, as well as variation in patients regarding characteristics, such as hospitalization, educational level, and geographical area within the Netherlands.

This study will be conducted according to Good Clinical Practice (GCP) guidelines. The prospective study was exempted from ethics approval for human subjects research by the medical ethics committee of Radboud University Medical Center (registration number 2020-7278) and is registered in the clinicaltrials.gov registry (NCT04735744). Informed consent was obtained from all patients prior to enrolment in the study.

Participants and data collection

For the prospective cohort study, all registered dietitians, exercise therapists, occupational therapists, physical therapists and speech and language therapists working in primary care in the Netherlands treating patients recovering from COVID-19 were eligible to participate. Between January 2021 and June 2021 professionals could sign up digitally for the cohort study. After signing up, professionals gained access to a secure research portal (password protected with personal log-in) specifically developed for the data collection (12).

Patients older than 18 years, recovering from symptomatological COVID-19 and self-reported activity limitations and/or participation restrictions and receiving allied healthcare, could enrol in the study by: *(i)* signing up digitally after an invitation by their treating allied health professionals, or *(ii)* signing up on their own initiative, whereupon the research team invited their treating health professional to participate. Subsequently, patients downloaded the specially designed application (digital data collection environment) on their smartphones or through a web-application and were requested to complete the enrolment steps. Patients with no access to, or lack of ability to work with, the digital tools were invited to complete the questionnaires on paper and return them by post.

Outcome measures

The outcome measures selected for this study have been categorized into primary outcome domains and corresponding measures, secondary outcome domains and corresponding measures and descriptive outcomes (see Appendix II). To evaluate allied healthcare in patients recovering from COVID-19, 4 primary outcome domains were selected: participation, HRQoL, fatigue, and physical functioning. Table I gives an overview of all outcomes and corresponding selected measures.

Primary outcome domains and corresponding measures.

- *Participation:* Participation is the primary outcome measure in the prospective study, and is measured with the Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P) (13). The USER-P is a 31-item questionnaire reflecting a patient's daily life distributed between frequency, restrictions and satisfaction subscales. Total scores range from 0 to 100, with higher scores indicating more participation. Effect sizes of 0.49 for improvements on the restrictions scale, and 0.36 on the satisfaction scale have been reported (14, 15).
- *Health-related quality of life:* HRQoL is measured with the EQ-5D-5L, which will also be used in the cost-consequence analysis and cost-outcome description. The EQ-5D-5L is a 5-item questionnaire measuring a person's health state in terms of 5 dimensions of health. An EQ-5D summary index (also known as a utility score) will be estimated by applying the Dutch value set that attaches values (weights) to each of the levels in each dimension, ranging from the worst health state (55555) to the best health state (11111). Predicted values for the Dutch population can range from –0.446 to 1, where 1 represents a health state that equals "full health" and 0 represents "death". Negative values indicate that a health state is perceived as worse than "death" (16). Furthermore, the study will also calculate the EQ visual analogue scale (VAS), which ranges from 0 to 100, and is a self-reported scale about the health status of patients.
- *Fatigue:* The Fatigue Severity Scale (FSS) evaluates fatigue. On a 9-item scale, the severity of fatigue and its impact on a person's activities and lifestyle is assessed in patients with a variety of disorders. Higher scores indicate greater fatigue. Estimates of the minimally important difference for the FSS range between 6.4% and 12.6% of the maximum FSS score (17).
- *Physical functioning:* is assessed with the PROMIS Physical Functioning Short Form 10b; a general primary outcome measure to evaluate limitations in physical functioning. The questionnaire measures self-reported functioning of one's upper extremities

Table I. Overall outcome measures and endpoints for the prospective cohort study on allied healthcare for patients recovering from COVID-19 in primary care

Profession	Domain	Measure	Baseline	End of treatment	3 months	6 months	9 months	12 months
Primary outcome measures								
Total cohort	Participation	USER-P	×		×	×		×
	Quality of life	EQ-5D-5L	×		×	×		×
	Fatigue	FSS	×		×	×		×
	Physical functioning	PROMIS FF Short Form 10b	×		×	×		×
	Costs	Cost questionnaire			×	×	×	×
Secondary outcome measures								
Total cohort	Psychological well-being	HADS	×	×	×	×	×	×
PT/ET	Physical functioning	PROMIS FF Short Form 10b	×		×	×		×
PT/ET	Activities	PSFS	×	×				
PT/ET	Exercise capacity	6MWT	×	×				
		SPPB	×	×				
PT/ET	Muscle strength	5TSTS	×	×				
		HHD	×	×				
DI	Nutritional status	BMI	×	×				
		SARC-F (Sarcopenia)	×	×				
		VAS appetite, taste and smell	×	×				
			×	×				
		BSC	×	×				
		BIA	×	×				
		Nutritional goals						
DI	Global assessment	PG-SGA SF	×	×				
SLT	Voice problems	VHI	×	×				
		MPT	×	×				
SLT	Swallowing problems	DHI	×	×				
		MSS	×	×				
OT	Activities	COPM	×	×				×
		PRO-ergo	×	×				
OT	Functioning	AMPS	×	×				
		PRPP	×	×				
OT	Cognitive functioning	CoCo-P	×	×				×

USER-P: Utrecht Scale for Evaluation of Rehabilitation Participation; EQ-5D-5L: EuroQol-5 Dimensions-5 Levels; FSS: Fatigue Severity Scale; PROMIS: Patient-Reported Outcomes Measurement Information System FF Short Form 10b; HADS: Hospital Anxiety and Depression Scale; PSFS: Patient Specific Functioning Scale; 6MWT: 6-minute walk test; SPPB: Short Physical Performance Battery; SWT: Shuttle Walk Test – incremental and endurance; 5TSTS: 5 times sit-to-stand test; HHD: Hand Held Dynamometer; BMI: body mass index; SARC-F: Strength, Assistance with walking, Rise from a chair, Climb stairs and Falls; VAS: visual analogue scale; BSC: Bristol Stool Chart; BIA: bio-electrical impedance analysis; PG-SGA: Patient-Generated Subjective Global Assessment short form; VHI: Voice Handicap Index; MPT: Maximum Phonation Time; DHI: Dysphagia Handicap Index; MSS: maximum swallowing speed; COPM: Canadian Occupational Performance Measure; PRO-ergo: Patient Reported Outcome-ergo; AMPS: Assessment of Motor and Process Skills; PRPP: Perceive, Recall, Plan, Perform; CoCo-P: Cognitive Complaints – Participation; Physical Therapist (PT) Exercise Therapist (ET) Dieticians (DI) Speech and Language therapists (SLT) Occupational Therapist (OT).

(dexterity), lower extremities (walking or mobility), and central regions (neck, back), as well as instrumental activities of daily living, such as carrying out errands (18).

Secondary outcome domains and corresponding measures. The Hospital Anxiety and Depression Scale (HADS) was used to assess psychological well-being (19). The HADS measures depression and anxiety in both inpatients and outpatients and in community settings. It contains 14 statements describing symptoms of depression and anxiety. Response options for each question range from 0 to 3 points and ask patients about their agreement with the statements or how often they apply. There are 7 statements each for depression and anxiety. A HADS score ≥ 11 indicates a probable clinical diagnosis of depression or anxiety (19).

Costs. Costs are measured from both a societal and a healthcare perspective. From the societal perspective, costs include the costs of the identified trajectories, other healthcare services (i.e. primary healthcare, secondary healthcare, and medication), informal care, as well as productivity loss from unpaid and paid work (i.e. absenteeism and presenteeism). From a healthcare perspective, only costs accruing to the formal Dutch healthcare sector are included. Costs of the identified trajectories will be micro-costed, meaning that detailed data are gathered on the types and volume of resources consumed, as well as their respective unit prices. All other types of resource use will be assessed using retrospective cost questionnaires and will be valued in accordance with the Dutch Manual of Costing (20, 21).

Profession-specific outcome measures. To evaluate outcomes specific to the context of the different allied health professionals, profession-specific outcome measures. An overview of the profession-specific outcome domains and corresponding measures is shown in Table I.

Sample size and power analysis

The power calculation is based on estimating clinically relevant differences in recovery on the restrictions scale and the satisfaction scale of the USER-P. In

patients with a variety of health conditions receiving outpatient rehabilitation, reported improvements in the scores on the restrictions scale and the satisfaction scale were 9.6 (SD 17.8) and 6.1 (SD 15.6) points, respectively (14, 15). A 5-point difference on 1 of these USER-P scales is assumed to be clinically relevant for COVID-19 patients. The required sample size to measure a 5-point difference between baseline and 6-months with a 2-sided alpha of 0.05 and power (1-beta) of 0.80 was based on prior studies with the USER-P, indicating a sample size of 90 patients to detect a change of 5 points on the USER-P if patients are treated by 1 allied health professional (14, 15). Because patients in the current study are potentially treated by different allied health professionals, it is necessary to correct for a therapist effect through clustering of patients. Intra-cluster coefficients (ICCs) in outcome measurement ranges from 0.00 to 0.15, resulting in a larger adjusted sample size when ICCs are higher (22). Assuming that the ICC may be as high as 0.15 and therapists may include 10–20 patients, the adjusted required sample size would be 212–414. We expect to include 1,315 patients in the study based on expected referrals of patients with COVID-19 to allied health professionals (23). This expected sample allows for subgroup analyses of outcomes per profession for the profession-specific and secondary outcomes and enables inclusion of relevant categorical variables (e.g. comorbidity and COVID-19 severity) in multivariable (logistic) models to explore differences between responders and non-responders, while keeping the risk of overfitting low (24).

Data analysis

Quantitative analysis. Descriptive statistics (means and SDs, medians and interquartile ranges (IQRs) and counts and percentages, where applicable) will be used to provide an in-depth description of baseline patient characteristics overall and per allied health profession. Quantitative data analysis will be used to assess the recovery of patients with COVID-19 after allied healthcare, based on within group pre- and post-measurements. The primary comparison assessing recovery is based on the change in participation levels on the USER-P from baseline to 6 months. The study will also evaluate recovery on the primary profession-specific outcomes, with 6 months as the primary endpoint. In secondary analyses, 12-month changes on USER-P will be evaluated.

Estimations of recovery will be modelled using mixed linear and logistic regression analysis for continuous outcomes and dichotomous outcomes, respectively. Analyses will be based on SDs (i.e. mean difference, 95% confidence intervals (95% CI) or odds ratio (OR) with 95% CI and *p*-value) in recovery for the different comparisons (see research questions), and on clinically relevant changes in the outcomes. For the USER-P the study assumes that a 5-point difference on each of the scales is clinically relevant for patients with COVID-19.

For each care trajectory (mono- and/or multi-disciplinary), there will be differences in the demographic profile and underlying symptoms of patients seen by (combinations of) the 5 different allied healthcare professional groups. Therefore, the study will explore clustering of patients within the different allied healthcare groups by fitting hierarchical models with a random group effect. The study will use a model with a random intercept and all other variables fixed. Furthermore, using mixed models, the study will assess potential differences between subgroups of patients by including the following parameters as interacting factors with time: severity of COVID-19, mono- vs multi-disciplinary treatment and specific treatment programmes. Multidisciplinary care is defined as any combination of 2 or more allied health professionals with overlapping care trajectories during the initial 4 months of treatment after COVID-19. Outcomes will be a case-mix adjusted for age, sex and relevant comorbidities. Finally, the study will conduct specific subgroup analyses per allied health profession to evaluate changes on the profession-specific and secondary outcomes and to identify potential effect-modifiers. Multivariable (logistic) modelling will be used to distinguish responders and non-responders.

For the cost analysis, it is not possible for the study to conduct a full economic evaluation due to the lack of a control group. Instead *(i)* a cost description, *(ii)* a cost-consequence analysis, and *(iii)* a cost-outcome description will be performed. The cost description will describe the costs of the various trajectories. The cost-consequence analysis will present a range of disaggregated costs and a range of outcomes, while the cost-outcome description will compare the individuals' costs with their respective number of quality-adjusted life years (QALYs) gained (20). For the cost-consequence analysis, the number of QALYs gained during follow-up will be estimated using the "area under the curve approach" (20). Minimally important differences for the EQ-5D in patients with a chronic disease (e.g. diabetes) have been estimated in a range between 0.03 and 0.05 (25). As cost data tends to be heavily skewed, uncertainty estimates will be based on non-parametric bootstrapping.

Qualitative analysis. All interviews and focus groups will be audio-recorded and transcribed verbatim. Transcripts will be analysed using thematic analysis with an inductive approach (Braun & Clarke 2006). Through the coding process using Atlas.ti 9.0 software the study will facilitate the coding process by

organizing the codes, identify initial categories, and maintaining a coding framework. Categories and themes will be critically discussed and reviewed by the qualitative research team.

Text-mining

Finally, the study will explore whether additional data can be obtained through text-mining of open text fields in electronic health records (EHRs) of allied health professionals. Text-mining might enable collection of additional data regarding outcomes on the level of functioning (26).

PRELIMINARY STUDY RESULTS

The recruitment period for the quantitative prospective cohort study was 29 March 2021 to 19 June 2021. In total 897 allied health professionals signed up to participate. A description of the prospective cohort is shown in Table II. The baseline characteristics of the study cohort are set out below using descriptive statistics.

During the inclusion period, 1,451 unique patients were recruited who, in total, received 1,708 treatment trajectories by 1 or more allied health professionals. The trajectories included physical/exercise therapy (59%), occupational therapy (21%), dietetic therapy (13%) and/or speech and language therapy (7%). In total, 57% of participants were female, the average age was 49 years (SD 13), and most participants (73%) were referred for allied healthcare by their general practitioner. Furthermore, 974 (67%) participants reported mild/moderate severity of symptoms during the infection period and 988 (77%) participants had not been hospitalized during the infection period.

Table III shows the mean/median/T scores and SD/interquartile range (IQR) of the participating patients at baseline for the outcome domains and corresponding measures. The patients-reported outcomes on the USER-P frequencies scale were: mean 28 (SD 10), restrictions scale: mean 66 (SD 19) and satisfaction scale: mean 39 (SD 16). Outcomes on the EQ-VAS were: mean 56 (SD 18), FSS: median 5.6 (IQR 5.0–6.3), the PROMIS Physical Functioning: T-score 35 (IQR 28–40), the HADS anxiety: mean 7.1 (SD 4.5) and HADS depression: mean 7.3 (SD 4.2).

Table II. Description of the prospective cohort study on allied healthcare for patients recovering from COVID-19 in primary care at baseline provided by allied health professionals

	Total prospective cohort
Patients, *n*	1451
Treatment trajectories, *n*	1708
Physical therapy/exercise therapy	1005
Occupational therapy	364
Dietary care	224
Speech and language therapy	115
Allied healthcare professionals, *n*	896
Sex, *n* (%)	
Male	475 (32.7)
Female	825 (56.9)
Missing	151 (10.4)
Age, mean ± SD	49.1 ± 13.0
Referring physician, *n* (%)	
General practitioner	1061 (73.1)
Pulmonologist	113 (8.7)
Internist	8 (0.6)
Rehabilitation physician	34 (2.6)
Elderly care physician	9 (0.7)
Direct access to allied healthcare	10 (0.8)
Other referral	59 (4.6)
Unknown	1 (0.1)
Missing	156 (10.8)
COVID-19 severity, *n* (%)	
Mild/moderate	974 (67.1)
Severe	268 (18.5)
Critical	38 (3.0)
Missing	171 (11.8)
Admission to hospital for COVID-19 infection, *n* (%)	
Hospitalized including IC-treatment	87 (6.0)
Hospitalized	210 (16.3)
Not hospitalized	988 (76.9)
Missing	166 (11.4)

n: number; SD: standard deviation; IC: Intensive Care.

DISCUSSION

By collecting mixed-methods data, the prospective study aims to establish an evidence-base for standalone or combined allied healthcare treatment of patients recovering from COVID-19, by identifying their health problems and their respective recovery trajectories. The results will provide insight into the recovery of patients treated by allied health professionals in Dutch

Table III. Primary outcome measures of the participating patients at baseline

Outcome measure	Baseline
USER-P[a], mean (SD)	[b]*n* = 1279
Frequency scale	27.5 (10.4)
Restrictions scale	65.8 (19.3)
Satisfaction scale	39.4 (16.3)
EQ-VAS, mean (SD)	[b]*n* = 1302
	55.6 (17.8)
FSS, median (IQR)	[b]*n* = 1298
	5.8 [5.1-6.3]
PROMIS, T-score (IQR)[c]	[b]*n* = 1291
	37.9 (33.5-41.5)
HADS anxiety, mean (SD)	[b]*n* = 1282
	7.1 (4.5)
HADS depression, mean (SD)	[b]*n* = 1282
	7.3 (4.2)

USER-P: Utrecht Scale for Evaluation of Rehabilitation Participation EQ-VAS: EuroQol Visual Analogue Scale FSS: Fatigue Severity Scale PROMIS: Patient-Reported Outcomes Measurement Information System; HADS: Hospital Anxiety and Depression Scale; SD: standard deviation; IQR: interquartile range.

[a]All 3 scales have a score range of 0–100, with higher scores reflecting better participation (higher frequency, less restrictions, higher satisfaction).

[b]Data were not fully available for all patients: the *n* within the table depicts the number of patients with available data.

[c]PROMIS instruments are always expressed as a score relative to the mean of a group (T-score). A T-score is a standardized score. In this process, the mean score in a population is assigned the value 50. The standard deviation (SD) is set equal to 10 points. In a normal distribution, 95% of the scores of people in the population are between the mean plus or minus 2 SD, in this case between the values 30 and 70. Values below 30 or above 70 therefore occur in less than 5% of the population.

primary care, and will enable existing guidance to be updated, or new guidance developed to provide evidence-based recommendations for allied health professionals, referrers and other relevant stakeholders.

To our knowledge, this is the first study to present the outcomes of patients recovering from a COVID-19 infection who are treated by allied health professionals in primary care. Preliminary findings indicate that patients in the study cohort report severe restrictions in activities of daily living compared with previous research in other patient populations. All subscales of the USER-P showed more restrictions in participation in comparison with patients with physical disabilities treated in outpatient clinics of rehabilitation centres (27). For the EQ-VAS the participants in the current study scored 25 points lower than norm values in the Dutch population based on mean scores and age (28). The outcomes on the FSS showed that 94% of patients in the study cohort scored 4 or higher, indicating moderate-to-high fatigue impact (29). Furthermore, 41% of patients reported symptoms of anxiety and 46% reported symptoms of depression using a cut-off value of ≥8 on the HADS subscales (30, 31). Overall these initial data suggest that the burden of illness in patients recovering form COVID-19 infection is rather substantial.

This study faces several challenges. The major expected challenge is to obtain sufficient subgroup data per allied health profession and to minimize missing data. Given the fluctuating course of COVID-19, the development of new (and hopefully better) treatment strategies and the emergence of new variants of COVID viruses is of utmost importance to rapidly fill the cohort with a comparable sample of patients and treatments for a stable baseline and treatment course. We therefore actively approached allied health professionals to include their patients in a timely manner and to stimulate adherence to protocol. Obtaining a complete dataset for each patient in the basic and detailed registration is fundamental. We therefore worked with professional bodies of allied health professionals and regional networks to optimize patient inclusion and completeness of the data.

Another challenge is to ensure an integrated approach in the evaluation of allied healthcare in patients recovering from COVID-19. To facilitate an integrated approach, we have established an interdisciplinary consortium with participants from all 5 allied health professions (dietitians, exercise therapists, physical therapists, occupational therapists, speech and language therapists) reflecting practice, policy, research and education. Patient representatives are involved as partners and were involved in developing the research proposal. An advisory group has been installed with multiple stakeholders including patient representatives, professional bodies, other healthcare professions, health insurers and policy makers. The role of the advisory group is to provide feedback on different aspects of the study from a stakeholder's perspective. In collaboration with the professional bodies of allied health professionals recommendations have been disseminated via newsletters, social media, websites and journals of the professional bodies. E-learning modules haven been developed to address monodisciplinary and multidisciplinary treatment of patients with COVID-19 by allied health professionals.

In conclusion, this will be the first comprehensive study to longitudinally evaluate the recovery trajectories and related costs of patients recovering from COVID-19 who are treated by allied health professionals in the Netherlands. The study will provide insight into the severity of restrictions and complaints at baseline (start of therapy) and provide evidence for the optimal strategy to treat patients recovering from COVID-19 infection, including which patients benefit, and to what extent, from treatment, and which factors might impact their recovery course over time.

ACKNOWLEDGEMENTS

Funding

We acknowledge ZonMW for funding this research (10390062010001).

REFERENCES

1. Webber SC, Tittlemier BJ, Loewen HJ. Apparent Discordance between the Epidemiology of COVID-19 and Recommended Outcomes and Treatments: A Scoping Review. Phys Ther 2021; 101: 1–15. DOI: 10.1093/ptj/pzab155
2. Taquet M, Dercon Q, Luciano S, Geddes JR, Husain M, Harrison PJ. Incidence, co-occurrence, and evolution of long-COVID features: A 6-month retrospective cohort study of 273,618 survivors of COVID-19. PLoS Med 2021; 18: 1-9. DOI: 10.1371/journal.pmed.1003773
3. National Institute for Health and Care Excellence: Clinical Guidelines. COVID-19 rapid guideline: managing the long-term effects of COVID-19. London: National Institute for Health and Care Excellence (UK) Copyright © NICE 2020., 2020. DOI: NBK567261
4. Greenhalgh T, Knight M, A'Court C, Buxton M, Husain L. Management of post-acute covid-19 in primary care. BMJ 2020; 370: 1-10. DOI: 10.1136/bmj.m3026
5. Sisó-Almirall A, Brito-Zerón P, Conangla Ferrín L, Kostov B, Moragas Moreno A, Mestres J, et al. Long Covid-19: Proposed Primary Care Clinical Guidelines for Diagnosis and Disease Management. Int J Environ Res Public Health 2021; 18: 1-7. DOI: 10.3390/ijerph18084350
6. Carfì A, Bernabei R, Landi F. Persistent Symptoms in Patients After Acute COVID-19. JAMA 2020; 324: 603-605. DOI: 10.1001/jama.2020.12603
7. Maxwell E. Living with COVID19: a dynamic review of the evidence around ongoing COVID19 symptoms. National Institute for Health Research, UK, 2020; 7: 1-8. DOI: 10.3310/themedreview_41169

8. Goërtz YMJ, Van Herck M, Delbressine JM, Vaes AW, Meys R, Machado FVC, et al. Persistent symptoms 3 months after a SARS-CoV-2 infection: the post-COVID-19 syndrome? ERJ Open Research 2020; 26: 1-13. DOI: 10.1183/23120541.00542-2020.
9. KNGF position statement physical therapy in patients recovering from COVID-19. 2020 [cited 11/01/2021]; Available from: https://www.kngf.nl/binaries/content/assets/kennisplatform/onbeveiligd/themapagina-covid/kngf-standpunt_fysiotherapie_bij_covid-19_29032022.pdf.
10. Position statement occupational therapy in patients recovering from COVID-19. 2021 [cited 11/01/2021]; Available from: https://info.ergotherapie.nl/file/download/default/6A5E0AC0401E6972DA637BB919F13500/26-01-21%20-%20Handreiking%20ergotherapie%20bij%20COVID-19%20in%20de%20herstelfase%20-%20versie%20januari%202021.pdf.
11. Position statement COVID-19 version 1.4. 2020 [cited 10/01/2021]; Available from: https://www.nvlf.nl/wp-content/uploads/sites/2/2020/06/Factsheet-Intramurale-instellingen.pdf.
12. Your Research™. [cited 01/20/2022]; Available from: https://www.yourresearch.com/about-your-research-company-compliance.
13. Post MW, van der Zee CH, Hennink J, Schafrat CG, Visser-Meily JM, van Berlekom SB. Validity of the utrecht scale for evaluation of rehabilitation-participation. Disabil Rehabil 2012; 34: 478-485. DOI: 10.3109/09638288.2011.608148
14. van der Zee CH, Baars-Elsinga A, Visser-Meily JMA, Post MWM. Responsiveness of two participation measures in an outpatient rehabilitation setting. Scand J Occup Ther 2013; 20: 201-208. DOI: 10.3109/11038128.2012.754491
15. van der Zee CH, Kap A, Rambaran Mishre R, Schouten EJ, Post MW. Responsiveness of four participation measures to changes during and after outpatient rehabilitation. J Rehabil Med 2011; 43: 1003-1009. DOI: 10.2340/16501977-0879
16. Versteegh MM, Vermeulen KM, Evers SMAA, de Wit GA, Prenger R, Stolk EA. Dutch Tariff for the Five-Level Version of EQ-5D. Value Health 2016; 19: 343-352. DOI: 10.1016/j.jval.2016.01.003
17. Rooney S, McFadyen DA, Wood DL, Moffat DF, Paul PL. Minimally important difference of the fatigue severity scale and modified fatigue impact scale in people with multiple sclerosis. Multiple sclerosis and related disorders 2019; 35: 158-163. DOI: 10.1016/j.msard.2019.07.028
18. Terwee CB, Roorda LD, de Vet HC, Dekker J, Westhovens R, van Leeuwen J, et al. Dutch-Flemish translation of 17 item banks from the patient-reported outcomes measurement information system (PROMIS). Qual Life Res 2014; 23: 1733-1741. DOI: 10.1007/s11136-013-0611-6
19. Snaith RP. The Hospital Anxiety And Depression Scale. Health and quality of life outcomes 2003; 1: 29. DOI: 10.1186/1477-7525-1-29
20. Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. Methods for the Economic Evaluation of Health Care Programmes: OUP Oxford, 2015.
21. Kanters TA, Bouwmans CAM, van der Linden N, Tan SS, Hakkaart-van Roijen L. Update of the Dutch manual for costing studies in health care. PloS one 2017; 12: 1-12. DOI: 10.1371/journal.pone.0187477
22. Campbell M, Grimshaw J, Steen N. Sample size calculations for cluster randomised trials. Changing Professional Practice in Europe Group (EU BIOMED II Concerted Action). J Health Serv Res Policy 2000; 5: 12-16. DOI: 10.1177/135581960000500105
23. National Health Care Institute - Dutch allied healtchare for patients recovering from COVID-19. [cited 10/01/2021]; Available from: https://www.zorginstituutnederland.nl/Verzekerde+zorg/paramedische-herstelzorg-na-covid-19.
24. Gnoth A, Kalisvaart A, van Ginkel-Res A, Wieman B, Horstman D, Wierdsma N, ten Have H , Kruizenga H, van Teeffelen J, Brouwer K, van Zutphen L, Rothkegel M, de van der Schueren M, Runia S. Treatment plan of dietitian at COVID-19 after hospital discharge The recovery phase after discharge from hospital: dietetics treatment in (Post) COVID-19 patients in a rehabilitation center. 2021 [cited 11/01/2021]; Available from: https://nvdietist.nl/artikelen/behandelplan-van-dietist-binnen-paramedische-herstelzorg-covid-19/.
25. McClure NS, Sayah FA, Ohinmaa A, Johnson JA. Minimally Important Difference of the EQ-5D-5L Index Score in Adults with Type 2 Diabetes. Value Health 2018; 21: 1090-1097. DOI: 10.1016/j.jval.2018.02.007
26. Meskers CGM, van der Veen S, Kim J, Meskers CJW, Smit QTS, Verkijk S, et al. Automated recognition of functioning, activity and participation in COVID-19 from electronic patient records by natural language processing: a proof- of- concept. Ann Med 2022; 54: 235-243. DOI: 10.1080/07853890.2021.2025418
27. van der Zee CH, Priesterbach AR, van der Dussen L, Kap A, Schepers VP, Visser-Meily JM, et al. Reproducibility of three self-report participation measures: The ICF Measure of Participation and Activities Screener, the Participation Scale, and the Utrecht Scale for Evaluation of Rehabilitation-Participation. J Rehabil Med 2010; 42: 752-757. DOI: 10.2340/16501977-0589
28. Janssen MF, Szende A, Cabases J, Ramos-Goñi JM, Vilagut G, König HH. Population norms for the EQ-5D-3L: a cross-country analysis of population surveys for 20 countries. The European Journal of Health Economics 2019; 20: 205-216. DOI: 10.1007/s10198-018-0955-5
29. Mathiowetz V, Matuska KM, Murphy ME. Efficacy of an energy conservation course for persons with multiple sclerosis. Arch Phys Med Rehabil 2001; 82: 449-456. DOI: 10.1053/apmr.2001.22192
30. Wynne SC, Patel S, Barker RE, Jones SE, Walsh JA, Kon SSC, et al. Anxiety and depression in bronchiectasis: Response to pulmonary rehabilitation and minimal clinically important difference of the Hospital Anxiety and Depression Scale. Chron Respir Dis 2020; 17: 1-9. DOI: 10.1177/1479973120933292
31. Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. Acta Psychiatr Scand 1983; 67: 361-370. DOI: 10.1111/j.1600-0447.1983.tb09716.x
32. CDC. Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19). Centers of Disease Control and Prevention. 2020 [cited 10/01/2021]; Available from: https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html.