Original Research Article

The Effect of Family Nursing Conversations as an Add-on to Multidisciplinary Treatment in Patients with Chronic Non-Cancer Pain: A Quasi-Experimental Trial

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Abstract

Introduction: Chronic non-cancer pain (CNCP) is a lifelong condition with radical consequences, calling for management involving patients' families. Interventions based on the family systems nursing framework by Wright and Leahey have proved beneficial in other populations but require investigation in a CNCP population. This trial assumed that family nursing conversations (FNCs) based on the family systems nursing framework would increase patients' and family members' self-efficacy concerning CNCP management.

Objective: To investigate whether an intervention with FNCs as an add-on to the usual multidisciplinary treatment of CNCP would have an effect on patients' and family members' self-efficacy. Additionally, to investigate any impact on family function, health-related quality of life, anxiety, and depression.

Methods: The trial applied a prospective non-blinded quasi-experimental design with two comparable groups of patients and family members: a historical control group (HCG) and an intervention group (IG). The intervention was executed by nurses employed at a multidisciplinary pain center in the Capital Region of Denmark. HCG data were collected before the nurses' intervention training. The primary outcome was self-efficacy. Secondary outcomes were family function, health-related quality of life, anxiety, and depression.

Results: In total, 58 patients and 85 family members were included. The primary outcome, self-efficacy, detected no statistically significant between-group differences in mean change for patients, $p = .990$, or family members, $p = .765$. A statistically significant effect in favor of the IG was found in between-group differences in mean change in patients' behavioral family

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function, $p = .034$, and anxiety, $p = .031$. No statistically significant between-group differences were detected in family members' secondary outcomes.

Conclusion: The intervention had no effect on patients' or family members' self-efficacy but a positive effect on patients' behavioral family function and anxiety. The intervention was deeply affected by the COVID-19 pandemic. Hence, any results should be interpreted with caution.

Keywords

pain, family caregiving, experimental design, research, self-efficacy

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Introduction

Chronic non-cancer pain (CNCP) is among the leading causes of disability and disease burden around the world (Mills et al., 2019). A 2017 survey of a Danish population ($n = 14{,}022$) found that CNCP (>6 months) had a prevalence of 27.8%, an increase of 8.3% since 2000 (Ekholm et al., 2022). CNCP may have comprehensive consequences for physical and mental health (Cohen et al., 2021; Mills et al., 2019; Morales-Espinoza et al., 2016; Toye et al., 2017), and it can negatively affect family function and strain caregivers (Cáceres-Matos et al., 2020; Suso-Ribera et al., 2020). Children growing up with parental CNCP are at a higher risk of developing CNCP themselves (Stone & Wilson, 2016). Therefore, CNCP is a condition with far-reaching consequences and a high level of complexity; unfortunately, it is rarely resolved by available treatment (Hysing et al., 2017; Turk et al., 2011). Treatment should take a biopsychosocial approach (Cohen et al., 2021), with an understanding of CNCP as a dynamic interaction between biological, psychological, and social factors (Cohen et al., 2021; Gatchel et al., 2007, 2014). The social dimension of the approach comprises family involvement. However, the benefit of family involvement seemed to be unexploited, with a gap in research investigating the effect of specific approaches to involve families.

Review of Literature

Current literature indicates that family involvement improves the management of CNCP, family function, and health-related quality of life (HrQoL) (Jongen et al., 2017; Rouhi et al., 2020; Swift et al., 2014; Tankha et al., 2020). A systematic review found significantly improved pain intensity following interventions targeting couples, such as psychoeducation, relaxation and meditation instruction, and the like (Smith et al., 2019). However, most studies included in the review were older than 10 years. A qualitative Danish study found that patients' need for family involvement was met only occasionally (Rønne, Horn, et al., 2021). Family systems nursing (FSN) is a comprehensive theoretical framework widely used to approach family involvement (Shajani & Snell, 2019). The framework considers the family as a system in which the family members continuously influence each other. Consequently, illness affects the entire family, which implies a shift in focus to encompass the family members and their internal interactions as the unit of care (Shajani & Snell, 2019). An integrative review from 2014 found that interventions based on the FSN framework improved family function and increased understanding, coping, and well-being (Ostlund & Persson, 2014). A randomized controlled trial found improved self-efficacy in patients with heart failure (Østergaard et al., 2018) and significantly better social support in the short, medium, and long terms (Østergaard et al., 2021). A study with a controlled before-and-after design with two groups of patients in home healthcare found significantly improved family function in both patients and family members (Broekema et al., 2021). For this reason, an intervention with family nursing conversations (FNCs) based on the FSN framework was assumed to be a beneficial approach for families afflicted by CNCP. However, the assumption required testing. Therefore, the present trial aimed to investigate whether an FNC intervention as an add-on to the usual multidisciplinary treatment of CNCP would have an effect on patients' and family members' self-efficacy compared to the usual multidisciplinary treatment. Additionally, to investigate any impact on family function, HrQoL, and anxiety/depression.

Methods

Design

The trial applied a prospective non-blinded quasi-experimental design (Barnighausen et al., 2017) with two comparable groups of patients and family members: a historical control group (HCG) and an intervention group (IG). Nurses employed in the trial setting executed the FNC intervention; however, the nurses were unfamiliar with the FSN framework and required training before conducting the intervention. HCG data were collected before the nurses' training to forestall pollution in the wake of it, while the IG data were collected subsequently. See Figure 1 for an overview of the trial's phases.

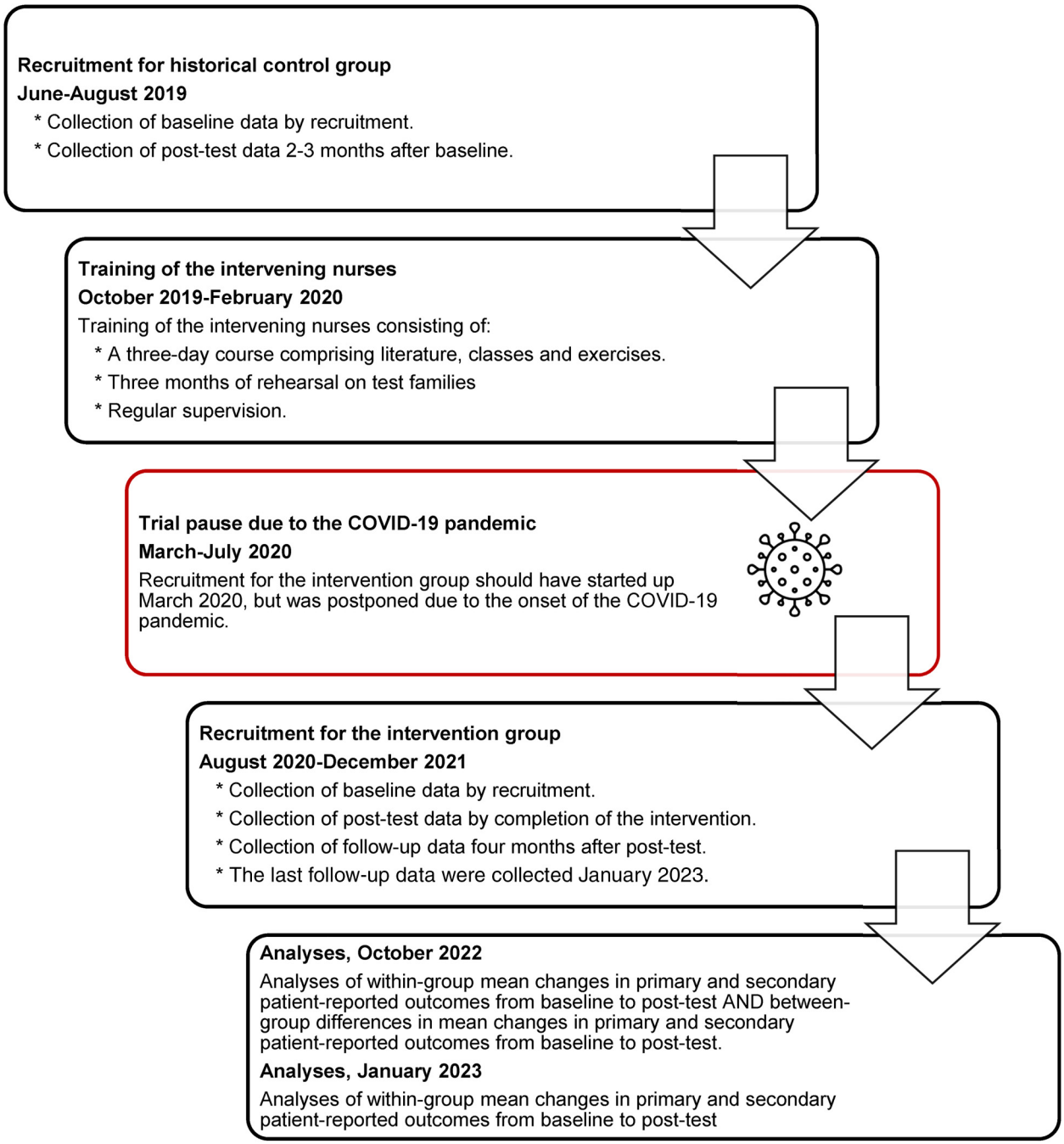

Figure 1. Overview of trial phases.

Research Question

Will an FNC intervention, as an add-on to the usual multidisciplinary treatment of CNCP have an effect primarily on patients' and family members' self-efficacy and reject a null hypothesis anticipating no improvement compared to those who only received usual multidisciplinary treatment? Secondarily, on family function, HrQoL, anxiety, and depression?

Trial Setting and Usual Care

The present trial was one study among three in the overall FANCOC-PAIN (FAmily Nursing COnversations Chronic non-cancer PAIN) study (Rønne, Esbensen, Brødsgaard, Biering-Sørensen, et al., 2023; Rønne, Esbensen, Brødsgaard, Rosenstrøm, et al., 2023). The trial was registered on ClinicalTrials.gov (NCT03981302) and was thoroughly described in a protocol paper (Rønne, Esbensen, et al., 2021).

The trial was conducted at a multidisciplinary pain center (MPC) in the Capital Region of Denmark, treating patients severely impaired by CNCP. According to usual multidisciplinary treatment, all patients were allocated a responsible physician and nurse, and depending on their specific health problems, they could also be linked to a physiotherapist, a social worker, and a psychologist. Patients could participate in psychologist- or physiotherapist-facilitated groups with other patients as a part of the treatment. In usual treatment, family involvement primarily took place when family members, with the consent of the patient, accompanied the patient to individual encounters. At the time of the HCG data collection, the MPC offered a service with a specific focus on the role of family members, consisting of two meetings, each lasting 2 hr, that patients could attend with their family members. At the time of IG data collection, the service was terminated. Instead, patients were encouraged to bring their family members to a general introduction to the MPC, also delivered at two meetings, each lasting 2 hr.

Sample

Patients referred to multidisciplinary treatment at the MPC within the prior 6 months were invited to participate in the trial with between one and three selected family members. In coherence with the definition in the FSN framework, family members were broadly perceived as close and meaningful relationships that were not limited to affiliations defined by genetics or law (Shajani & Snell, 2019). The nurses at the MPC asked the patients if they were interested in receiving information about the trial, and the first author contacted those who consented. Next, the interested patients asked their family members, who, after agreeing to participate, also were contacted by the first author.

Inclusion/Exclusion Criteria

Patients and family members who speak Danish and are at least 18 years of age were eligible to participate. Exclusion criteria included the inability to collaborate and provide consent or active participation in other family interventions. Together, the patient and the selected family members constituted a family unit, and inclusion in the study was possible only as part of a family unit. Patients and family members were perceived as included when all members of the family unit had delivered baseline data. The inclusion date was the deliverance of baseline data for the first member of the family unit.

Intervention

The intervention consisted of an FNC series with at least two and up to four FNCs at intended intervals of 3 weeks. The FNCs took place at the MPC with the family unit and one or two nurses, depending on the nurses' need for a co-nurse and other workloads. The intention was to support the family in reducing restrictive illness beliefs and to find new ways to manage the illness (Shajani & Snell, 2019; Wright & Bell, 2009). The framework was operationalized through the adjusted application of the Calgary models and intentional questioning based on Karl Tomm's linear and circular question types (Shajani & Snell, 2019; Tomm, 1988). The intervention content was described in a manual and a quick guide that was specifically developed for this trial by the first author. Each FNC lasted 1.5 hr, including the nurses' time to document the FNC content. As part of the documentation, the nurses were asked to indicate which of the 18 components they used during the FNC series to assess the intervention fidelity. An overview of the FNC intervention's components is presented in Figure 2, which depicts the family units' exposure to the components, as documented by the nurses, for those who completed the FNC intervention.

The first author facilitated the training of the nurses based on the knowledge-to-action cycle (Duhamel, 2017) as a tool to translate the theoretical content of the FNC intervention into practice. The training consisted of a 3-day external course including literature, classes, and exercises, followed by 3 months of rehearsals with test families before the onset of the intervention. The nurses received regular supervision throughout the rehearsal and intervention periods from a nurse who specialized in the FSN framework and later a psychologist who undertook general supervision of the multidisciplinary personnel at the MPC. A thorough description of the intervention, including the nurses' training, is published elsewhere (Rønne, Esbensen, et al., 2021).

Primary Outcome

The primary outcome was *self-efficacy*, measured by the Danish version of the General Self-efficacy Scale (GSE) (Mikkelsen & Einarsen, 2002; Scholz et al., 2002). A change in the GSE was considered a sign of change in patients' and family members' restrictive beliefs after participation in the FNC intervention. The GSE scale consists of 10 items, each having four response categories. The score ranges from 10 to 40, with higher scores indicating stronger self-efficacy, but the scale does not operate with a cutoff score (Scholz et al., 2002; Schwarzer, 2014). The Cronbach's alpha in the Danish population was 0.87 (Scholz et al., 2002).

Secondary Outcomes

The secondary outcomes comprised family function, HrQoL, and anxiety/depression. *Family function* was measured by the Iceland-Expressive Family Functioning Questionnaire (ICE-EFFQ), based on the FSN framework (Sveinbjarnardottir et al., 2012). ICE-EFFQ has 17 items with five response options. The total score ranges from 7 to 85 and is produced

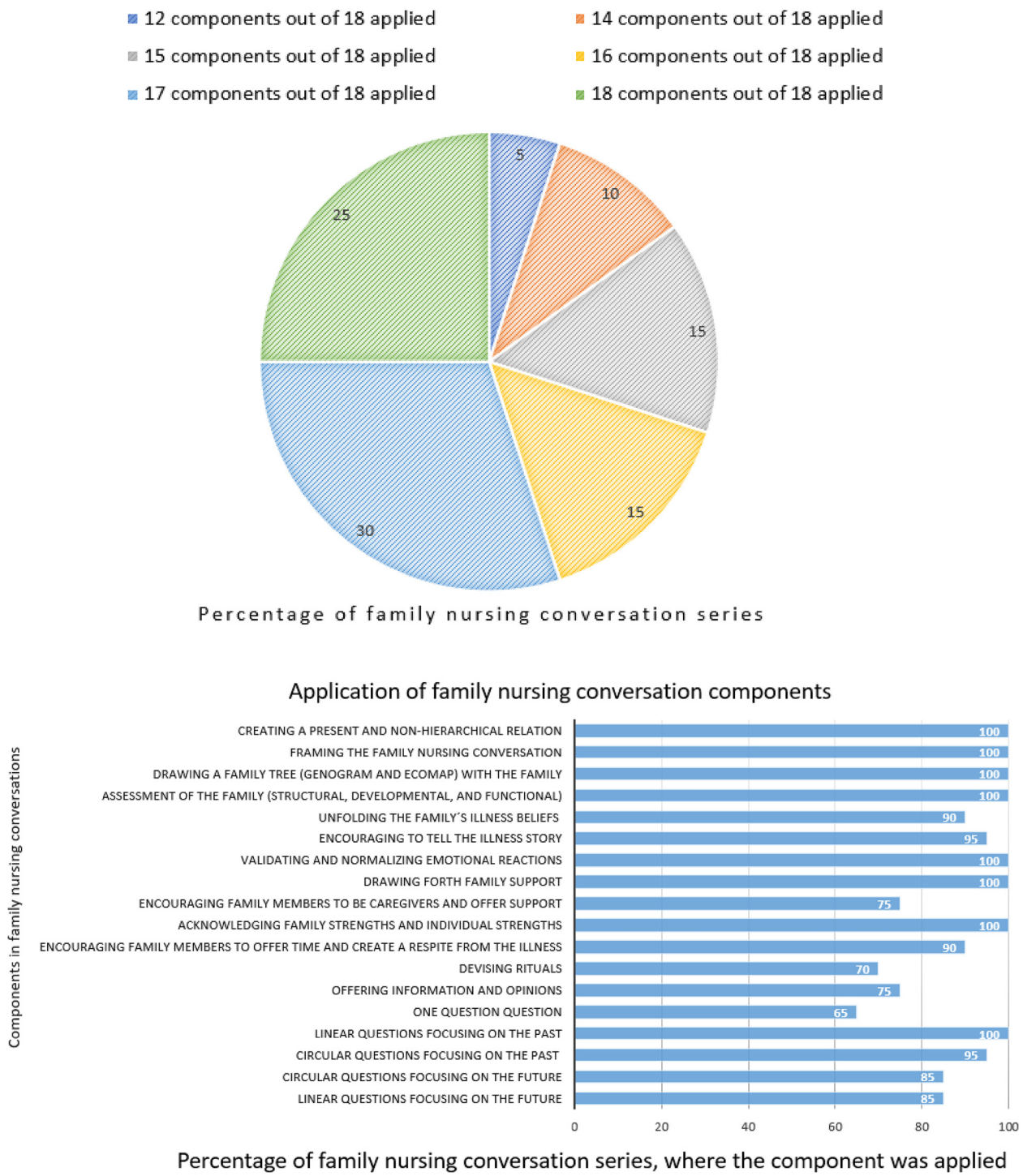

Figure 2. Intervention fidelity: the family units' exposure to the components during the series with family nursing conversations.

by scores in four categories: expressing emotions (score range 4–20), collaboration and problem-solving (score range 5–25), communication (score range 4–20), and behavior (score range 4–20). ICE-EFFQ was translated into Danish and validated with a Cronbach's alpha of 0.93 (Konradsen et al., 2018).

HrQoL was measured by the 12-item Short Form Health Survey (SF-12), consisting of two main categories of physical and mental health. Each main category comprises four health domains gathered in a physical component summary (PCS) and a mental component summary (MCS). The SF-12 raw scores were transformed into a *t*-score for PCS

and MCS. Scores above or below 50 correspond to scores above or below the 2009 mean U.S. general population score, and a higher score is associated with a better HrQoL (Maruish, 2012). SF-12 is the short form of the Danish-translated and validated 36-item Short Form Health Survey (SF-36) (Bjorner et al., 1998). High correlations between SF-36 and SF-12, ranging from 0.94 to 0.96 for physical health and from 0.94 to 0.97 for mental health, were found in nine European countries, including Denmark (Gandek et al., 1998).

Anxiety/depression was measured by the Hospital Anxiety and Depression Scale (HADS), consisting of two subscales: one for anxiety (HADS-A) with a Cronbach's alpha of 0.83 and one for depression (HADS-D) with a Cronbach's alpha of 0.82 (Bjelland et al., 2002; Zigmond & Snaith, 1983). Each subscale includes seven items with scores ranging from 0 to 3 and a total subscale score ranging from 0 to 21. Scores of 0–7 indicate no cases, 8–10 doubtful cases, and above 10 definite cases (Zigmond & Snaith, 1983). A Danish version can be obtained from the Mapi Research Trust (Mapi-trust.org). A newer Danish study on patients with cardiac diseases found Cronbach's alphas of 0.87 for HADS-A and 0.82 for HADS-D (Christensen et al., 2020).

Other Data

Socio-demographics comprised age, gender, country of origin, civil status, highest education, and occupation. Family members additionally reported their affiliation to the patient. Health information comprised both the duration and causation of CNCP and the number of self-reported comorbidities (patients) or diseases (family members), including anxiety and depression.

Sample Size

The sample size was based on the GSE and a power calculation for comparing mean changes in two independent groups. The minimal important difference was estimated to be 4.4 points, which was the difference between a mean GSE of 32.9 in an average Danish population (Scholz et al., 2002) and a mean GSE of 28.5 in 1,494 patients from a Norwegian outpatient pain clinic (Granan et al., 2019). The *SD* for change was determined to be 5.1 based on an *SD* of 5.7 (Granan et al., 2019) and an estimated correlation from baseline to post-test of 0.6. With a power of 80% and a significance level of 5%, the sample size was calculated to be 22 family units in each group. With an expected dropout of 20%, the final sample size was 28 family units in each group.

Data Collection

The chosen outcomes were used for patients as well as family members. Baseline socio-demographics, health information, and outcome data were collected in both groups. The HCG post-test outcome data were collected 2–3 months from baseline, corresponding to the estimated duration of an FNC series. In the IG, post-test outcome data were collected by completing the intervention, while follow-up outcome data were collected 4 months after the post-test. Questions concerning socio-demographics, health information, and the selected outcomes were gathered into one questionnaire used for data collection conducted by the first author through structured telephone interviews (Shuy, 2002; Singleton & Straits, 2002)

Statistical Analysis

Statistical analyses were guided by a statistician, handled in SPSS versions 25 and 29 for Windows, and conducted separately for patients and family members. The effect analyses were done for completed cases only. Because of the vulnerability of the study population, it would have been unethical to continue collecting data from those who discontinued, which predominantly was due to limited energy, overwhelming life circumstances, or other illnesses. However, within the analysis sample, the intention-to-treat principle was followed, which is why missing data in the analysis sample were replaced by simple imputation with series means. Sensitivity analyses with and without the replacement of missing data were conducted to detect the impact of using imputation. A *t*-test was used in both groups to identify changes in primary and secondary outcome variables from baseline to post-test and, in the IG, also to identify changes from baseline to follow-up and post-test to follow-up. Multiple regressions were used to analyze between-group mean differences in changes from baseline to post-test in primary and secondary outcome variables. First, mean changes from baseline to post-test were tested, one by one, for each variable in a model controlling for baseline together with the covariates of age, gender, country of origin, civil status, education, occupation, affiliation to the patient (family members only), pain duration, and number of self-reported comorbidities or diseases. Next, multiple regression analysis identified between-group differences for each outcome variable, adjusting for the group, baseline, and covariates from the first analysis with $p < 0.1$. Model control was conducted for both *t*-tests and regression analyses.

Ethical Considerations

The FANCOC-PAIN trial followed the declaration of Helsinki (World Medical Association, 2013). It was approved by the Committees on Health Research Ethics in the Capital Region of Denmark (record no. H-19016896) and the data storage by the Danish Data Protection Agency (record no. P-2019-508). Due to the European General Data Protection Regulation, data are only available from the corresponding author upon reasonable request.

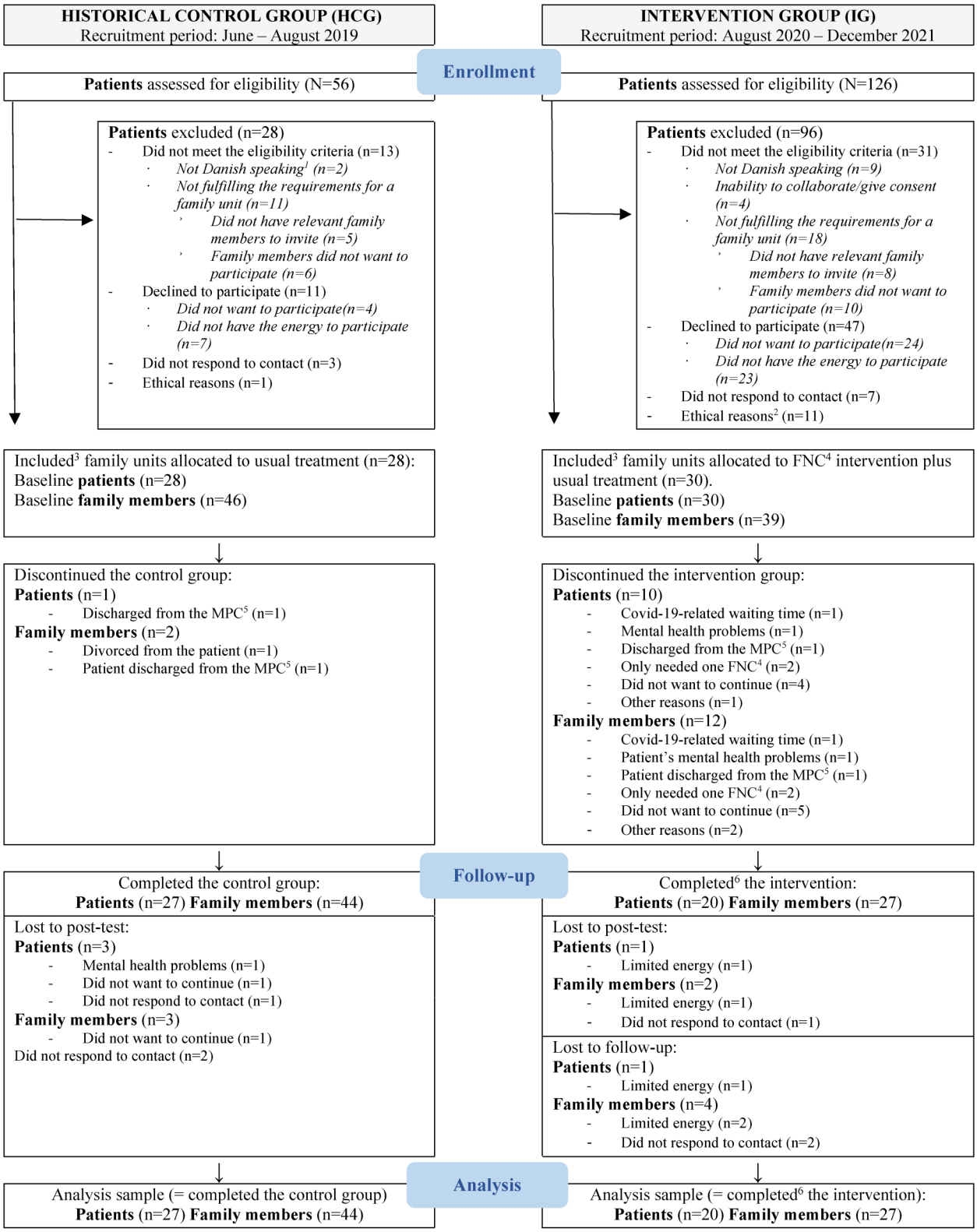

Figure 3. CONSORT flow diagram adjusted for the quasi-experimental trial. [1]More patients than the stated were excluded due to not speaking Danish. The amount is estimated to be six patients. [2]Ethical reasons comprised cases where the health professionals considered it would be inappropriate or harmful to contact the patients. [3]Included was defined as verbal consent to participate in the historical control group or the intervention group and delivery of baseline data from the patient and at least one family member. [4]Family nursing conversations. [5]Multidisciplinary pain center. [6]The intervention was perceived as completed for patients and family members if the family unit as a whole completed at least two family nursing conversations, including members of the family unit who only participated in one family nursing conversation. CONSORT = Consolidated Standards of Reporting Trials.

All participants received oral and written information from the first author. The information emphasized that participation was voluntary and that the participants could withdraw at any time without explanation or treatment consequences. The eligibility criteria that family members should be 18+ years of age could be deviated from if it was considered morally inappropriate to exclude a family member due to age. Consent was obtained from both patients and family members. The reporting of the results was guided by the Consolidated Standards of Reporting Trials (CONSORT) checklist, adjusted for the quasi-experimental design (Moher et al., 2010).

Results

Sample Characteristics

An overview of recruitment periods and eligible patients is displayed in the CONSORT flow diagram in Figure 3.

A total of 58 family units (58 patients and 85 family members) were included in the trial, with 28 patients and 46 family members in the HCG and 30 patients and 39 family members in the IG.

In the HCG, one patient and two family members discontinued the usual multidisciplinary treatment in the MPC. Thus, 27 patients and 44 family members completed the usual multidisciplinary treatment, of whom three patients and three family members were lost to post-test due to a wish to discontinue, mental health problems, or non-response (see Figure 3).

In the IG, 10 patients and 12 family members discontinued the intervention. Thus, 20 patients and 27 family members completed the intervention, of whom one patient and two family members were lost to the post-test (Figure 3), while one patient and four family members were lost to follow-up. The intervention was perceived as completed if the family unit completed at least two FNCs. Table 1 offers an overview of the baseline characteristics for patients and family members who completed the series, discontinued it, and the overall total.

The Impact of the COVID-19 Pandemic

The COVID-19 pandemic began at the same time that the recruitment for the IG was designed to get underway, in March 2020. As a result, the pandemic significantly affected how the intervention was conducted. Since family members were not allowed to enter the hospital for an extended period, the recruitment was postponed to August 2020, when the intervention started, despite the limitations resulting from continued restrictions. In fact, the pandemic had an off-and-on impact on the entire IG period. Only one family member could accompany the patient in the hospital for a time, which influenced how many family members could be selected (Figure 3). Further COVID-related shutdowns caused a considerable extension of the planned intervals between the FNCs and, as a result, the prolonged duration of the FNC series for a majority of the family units. In the HCG, the duration between inclusion and post-test ranged between 8 and 16 weeks (mean = 12.5 weeks) for patients and between 7 and 18 weeks (mean = 12.5 weeks) for family members. In the IG, the duration between inclusion and post-test ranged between 9 and 61 weeks (mean = 27.4 weeks) for patients and between 9 and 60 weeks (mean = 29.2 weeks) for family members. The number of patients and family members who completed the post-test within 18 weeks of baseline (corresponding to the highest interval in the HCG) amounted to 42% and 36%, respectively. For some family units, their decision to discontinue participation was due to extended periods and interruptions. In one family unit, two out of three of the FNCs were held as an online meeting, an alternative that grew out of the pandemic and allowed this patient to participate despite a high pain level.

Research Question Results

The quasi-experimental trial aimed to investigate whether an FNC intervention as an add-on to the usual multidisciplinary treatment of CNCP would have an effect on patients' and family members' self-efficacy compared to the usual multidisciplinary treatment. Additionally, to investigate any impact on family function, HrQoL, and anxiety/depression. The effect on primary and secondary outcomes is displayed in Tables 2 and 3 (patients and family members, respectively).

For the primary outcome, self-efficacy, the FNC intervention demonstrated no statistically significant within-group changes or between-group differences for patients (Table 2) or family members (Table 3).

For the patients' secondary outcomes, the mean value of ICE-EFFQ-behavior in the IG increased by 1.43 points (95% confidence interval [CI]: 0.51, 2.35), $p = .004$, from baseline to post-test (Table 2). From post-test to follow-up, it decreased by 0.42 (−0.88; 0.04). Still, the within-group change from baseline to follow-up of 1.01 (0.06; 1.96) was found statistically significant with $p = .038$. When adjusted for baseline and number of self-reported comorbidities, there was a statistically significant between-group difference in mean change of ICE-EFFQ-behavior of 1.16 points (95% CI: 0.09, 2.24), $p = .034$, indicating a possible, though not strong, positive effect of the intervention on behavioral family function (Table 2). The remaining ICE-EFFQ categories and total score did not demonstrate within-group changes or between-group differences of statistical significance (Table 2).

A statistically significant within-group change of 4.15 (95% CI: 0.74, 7.55), $p = .020$, was found in the IG in SF-12-PCS, followed by a further increase at follow-up. A statistically significant within-group change of 2.99 (95% CI: 0.50, 5.48), $p = .021$ was found in the HCG in SF-12-MCS (Table 2). No

Table 1. Patients' and Family Members' Baseline Characteristics.

	Patients HCG[a]			Patients IG[b]			Family members HCG[a]			Family members IG[b]		
	Completed ($n=27$)	Discontinued ($n=1$)	Total ($n=28$)	Completed ($n=20$)	Discontinued ($n=10$)	Total ($n=30$)	Completed ($n=44$)	Discontinued ($n=2$)	Total ($n=46$)	Completed ($n=27$)	Discontinued ($n=12$)	Total ($n=39$)
Sociodemographic												
Affiliation to the patient (family members), no. (%)												
Spouse/cohabitant							15 (34)	1 (50)	16 (35)	12 (44)	4 (33)	16 (41)
Boy/girlfriend							3 (7)		3 (7)	2 (7)	1 (8)	3 (8)
Ex-husband/wife								1 (50)	1 (2)		1 (8)	1 (3)
Parent							13 (30)		13 (28)	8 (30)	5 (42)	13 (33)
Child							8 (18)		8 (17)	3 (11)	1 (8)	4 (10)
Sibling							1 (2)		1 (2)			
Child in law										1 (4)		1 (3)
Friend							4 (9)		4 (9)	1 (4)		1 (3)
Gender, no. (%)												
Female	19 (70)		19 (68)	13 (65)	6 (60)	19 (63)	27 (61)	1 (50)	28 (61)	14 (52)	7 (58)	21 (54)
Male	8 (30)	1 (100)	9 (32)	7 (35)	4 (40)	11 (34)	17 (39)	1 (50)	18 (39)	13 (48)	5 (42)	18 (46)
Age, years, range/M	21–74/43.3	65	21–74/44.1	18–81/48.3	21–61/38.6	18–81/45.1	14–75/46.6	49–62/55.5	14–75/47.0	27–81/53.2	20–62/44.8	20–81/50.6
Country of origin, no. (%)												
Denmark	21 (78)	1 (100)	22 (79)	19 (95)	9 (90)	28 (93)	38 (86)	1 (50)	39 (85)	26 (96)	11 (92)	37 (95)
Another European country	4 (15)		4 (14)	1 (5)	1 (10)	2 (7)	3 (7)	1 (50)	4 (9)		1 (8)	1 (3)
Another country outside Europe	2 (7)		2 (7)				3 (7)		3 (7)	1 (4)		1 (3)
Civil status, no. (%)												
Living with a partner (marriage or cohabitation)	18 (67)		18 (64)	11 (55)	5 (50)	16 (53)	30 (68)	1 (50)	31 (67)	20 (74)	10 (83)	30 (77)
Children <25 years old **living at home**	7 (39)		7 (39)	1 (9)	2 (40)	3 (19)	11 (37)	1 (100)	12 (39)	5 (25)	2 (20)	7 (23)
Not living with a partner (marriage or cohabitation)	6 (22)	1 (100)	7 (25)	4 (20)	3 (30)	7 (23)	10 (23)	1 (50)	11 (24)	5 (19)	1 (8)	6 (15)
Children <25 years old **living at home**	1 (17)		1 (14)	1 (25)		1 (14)	4 (40)		4 (36)	1 (20)		1 (17)
Other[c]	3 (11)		3 (11)	5 (25)	2 (20)	7 (23)	4 (9)		4 (9)	2 (7)	1 (8)	3 (8)
Highest education level, no. (%)												
Did not finish primary school	2 (7)		2 (7)	2 (10)		2 (7)	2 (5)		2 (4)	2 (7)		2 (5)
Primary school (7–10 years)	2 (7)	1 (100)	3 (11)	4 (20)	1 (10)	5 (17)	3 (7)	1 (50)	4 (9)		2 (17)	2 (5)
Secondary school (11–13 years)	9 (33)		9 (32)	6 (30)	8 (80)	14 (47)	23 (52)		23 (50)	16 (59)	8 (67)	24 (62)
Bachelor's degree or higher	14 (52)		14 (50)	8 (40)	1 (10)	9 (30)	16 (36)	1 (50)	17 (37)	9 (33)	2 (17)	11 (28)
Occupation, no. (%)												
Employed	5 (19)		5 (18)	3 (15)	3 (30)	6 (20)	23 (52)	2 (100)	25 (54)	17 (63)	4 (33)	21 (54)
Unemployed	12 (44)		12 (43)	1 (5)		1 (3)	4 (9)		4 (9)		1 (8)	1 (3)
Retired	4 (15)	1 (100)	5 (18)	10 (50)	1 (10)	11 (37)	10 (23)		10 (22)	8 (30)	2 (17)	10 (26)
Social welfare[d]	3 (11)		3 (11)	2 (10)	2 (20)	4 (13)					1 (8)	1 (3)
Other[e]	3 (11)		3 (11)	4 (20)	4 (40)	8 (27)	7 (15)		7 (15)	2 (7)	4 (33)	6 (15)
Health information												
Duration of the patient's CNCP[f]**, no. (%)**; years												
<2	2 (7)		2 (7)	5 (25)	3 (30)	8 (27)	2 (5)		2 (4)	7 (26)	5 (42)	12 (31)
2–5	9 (33)		9 (32)	6 (30)	4 (40)	10 (33)	14 (32)		14 (30)	4 (15)	3 (25)	7 (18)
5–10	6 (22)		6 (21)		2 (20)	2 (7)	7 (16)		7 (15)	8 (30)	2 (17)	10 (26)
>10	10 (37)	1 (100)	11 (39)	9 (45)		9 (30)	21 (48)	2 (100)	23 (50)	8 (30)		8 (21)
Unknown					1 (10)	1 (3)					2 (17)	2 (5)
Numbers of causations to CNCP[f]**, no. (%)**												
1	15 (56)	1 (100)	16 (57)	7 (35)	3 (30)	10 (33)	27 (61)	1 (50)	28 (61)	16 (59)	6 (50)	22 (56)
2	7 (26)		7 (25)	9 (45)	5 (50)	14 (47)	10 (23)	1 (50)	11 (24)	7 (26)	5 (42)	12 (31)
3	1 (4)		1 (4)	3 (15)	1 (10)	4 (13)				4 (15)	1 (8)	5 (13)
>3	1 (4)		1 (4)	1 (5)		1 (3)						
Unknown causation	3 (11)		3 (11)		1 (10)	1 (3)	7 (16)		7 (15)			
Causation of the patients CNCP[f]**, no. (%)**												
Trauma	8 (30)		8 (29)	9 (45)	6 (60)	15 (50)	15 (34)		15 (33)	10 (37)	8 (67)	18 (46)
Whiplash	1 (4)		1 (4)	3 (15)	1 (10)	4 (13)	1 (2)		1 (2)	3 (11)	1 (8)	4 (10)
Fibromyalgia	3 (11)		3 (11)		1 (10)	1 (3)	2 (5)		2 (4)		1 (8)	1 (3)
CRPS[g]				4 (20)	5 (50)	9 (30)				6 (22)	7 (58)	13 (33)

(continued)

Table 1. Continued.

	Patients HCG[a]			Patients IG[b]			Family members HCG[a]			Family members IG[b]		
	Completed ($n=27$)	Discontinued ($n=1$)	Total ($n=28$)	Completed ($n=20$)	Discontinued ($n=10$)	Total ($n=30$)	Completed ($n=44$)	Discontinued ($n=2$)	Total ($n=46$)	Completed ($n=27$)	Discontinued ($n=12$)	Total ($n=39$)
Backpain, slipped disc, spinal stenosis	7 (26)		7 (25)	11 (55)	2 (20)	13 (43)	7 (15)	1 (50)	8 (17)	9 (33)	1 (8)	10 (27)
Pain following spine surgery	2 (7)		2 (7)	2 (10)		2 (7)	3 (7)		3 (6)	3 (11)		3 (8)
Pain following other surgery	3 (11)		3 (11)	3 (15)		3 (10)	3 (7)		3 (7)	3 (11)		3 (8)
Pain following cancer treatment	1 (4)		1 (4)		1 (10)	1 (3)					1 (8)	1 (3)
Other causations	11 (41)	1 (100)	12 (43)	6 (30)		6 (20)	16 (36)	2 (100)	18 (39)	8 (30)		8 (21)
Self-reported comorbidities (patients)												
Self-reported diseases (family members) Amount, no. (%)												
0	9 (33)		9 (32)	6 (30)	5 (50)	11 (37)	22 (50)		22 (48)	10 (37)	4 (33)	14 (36)
1–3	16 (59)	1 (100)	17 (61)	13 (65)	5 (50)	18 (60)	22 (50.)	2 (100)	24 (52)	17 (63)	8 (67)	25 (64)
>3	2 (7)		2 (7)	1 (5)		1 (3)						
Diagnosed anxiety/depression (self-reported), no. (%)	8 (30)		8 (29)	7 (35)	1 (10)	8 (27)	6 (14)		6 (13)	3 (11)	3 (25)	6 (15)
Primary outcome												
Self-efficacy (GSE[h]), 10–40 points, *M* **(***SD***)**	27.4 (6.3)	32	27.5 (6.3)	25.9 (6.5)	27.8 (4.3)	26.5 (5.9)	33.1 (4.5)	32.5 (0.7)	33.0 (4.4)	33.0 (4.3)	29.9 (5.9)	32.0 (5.0)
Secondary outcomes												
Family function (ICE-EFFQ[i]), *M* **(***SD***)**												
Total score, 17–85 points	66.3 (11.4)	72	66.5 (11.2)	68.5 (10.1)	64.1 (11.5)	67.1 (10.6)	71.1 (7.5)	83.0	71.4 (7.6)	70.1 (12.1)	67.2 (12.2)	69.2 (12.0)
Expressing emotions, 4–20 points	16.5 (3.2)	19	16.6 (3.2)	16.7 (2.9)	16.6 (1.6)	16.6 (2.5)	17.8 (1.4)	17.0 (4.2)	17.8 (1.5)	17.2 (3.0)	16.6 (3.4)	17.0 (3.1)
Collaboration and problem-solving, 5–25 points	19.4 (3.7)	22	19.5 (3.7)	20.3 (2.9)	18.8 (5.4)	19.8 (3.9)	21.0 (2.9)	24.0	21.1 (2.)	20.3 (4.1)	19.3 (4.4)	20.0 (4.1)
Communication 4–20 points	14.4 (3.5)	14	14.4 (3.4)	15.8 (3.1)	13.6 (2.7)	15.1 (3.1)	15.6 (2.5)	19.0	15.6 (2.5)	15.6 (3.8)	15.8 (2.7)	15.6 (3.5)
Behavior 4–20 points	15.9 (3.3)	17	15.9 (3.2)	15.9 (2.9)	15.5 (2.8)	15.8 (2.9)	16.7 (2.5)	18.0 (2.8)	16.8 (2.5)	16.4 (2.9)	15.8 (2.9)	16.3 (2.9)
HrQoL[j] (SF-12[k]), *M* **(***SD***)**												
SF-12-PCS[l], *t*-score	29.7 (8.0)	53.5	30.5 (9.1)	27.2 (6.8)	35.6 (7.4)	30.0 (7.9)	49.5 (13.1)	53.7 (3.4)	49.7 (12.9)	49.8 (9.5)	52.6 (10.2)	50.5 (9.7)
SF-12-MC[m], *t*-score	39.5 (10.6)	44.6	39.7 (10.4)	45.4 (8.3)	45.1 (10.9)	45.3 (9.0)	50.2 (7.9)	50.0 (13.3)	50.2 (8.0)	50.7 (9.6)	45.5 (13.2)	49.1 (10.9)
Anxiety and depression (HADS[n]), *M* **(***SD***)**												
HADS-A[o], 0–21 points	9.5 (4.1)	8	9.4 (4.0)	7.8 (3.6)	7.8 (4.9)	7.8 (4.0)	5.4 (3.9)	2.5 (2.1)	5.3 (3.9)	5.1 (3.2)	6.8 (5.5)	5.7 (4.0)
HADS-D[p], 0–21 points	8.9 (3.8)	1	8.6 (4.0)	7.0 (3.8)	6.3 (4.9)	6.7 (4.2)	3.2 (3.3)	1.0 (1.4)	3.1 (3.3)	3.5 (3.2)	3.6 (4.0)	3.5 (3.4)

[a]Historical control group, [b]Intervention group, [c]Covers living with parents, living with a roommate or having a partner but living alone, [d]Public Danish social welfare arrangements to clarify working ability and support adherence to the labor market, [e]Covers studying, absent owing to illness and not registered, [f]Chronic non-cancer pain, [g]Complex regional pain syndrome, [h]General Self-Efficacy Scale, [i]Iceland Expressive Family Function Questionnaire, [j]Health-related quality of life, [k]Short Form [12-item], [l]Physical component summary, [m]Mental component summary, [n]Hospital Anxiety and Depression Scale, [o]Hospital Anxiety and Depression Scale for Anxiety, [p]Hospital Anxiety and Depression Scale for Depression.

Table 2. The Intervention Effect on Patients.

	HCG[a]: Within-group change from baseline to post-test	*p*	IG[b]: Within-group change from baseline to post-test	*p*	IG[b]: Within-group change from baseline to follow-up	*p*	IG[b]: Within-group change from post-test to follow-up	*p*	Differences between HCG[a] and IG[b] in mean change between baseline and post-test	*p*
Primary outcome										
Self-efficacy (GSE[c]), mean (lower; upper)										
Total score, 10–40 points	0.21 (−2.12; 2.55)	0.853	0.68 (−2.49; 3.85)	0.659	0.94 (−1.92; 3.80).	0.499	0.26 (−1.91; 2.44)	0.803	−0.02 (−3.36; 3.32)	0.990[l]
Secondary outcomes										
Family function (ICE-EFFQ[d]), mean (lower; upper)										
Total score, 17–85 points	1.12 (−1.93; 4.17)	0.457	2.82 (−0.62; 6.27)	0.102	2.19 (−0.93; 5.31)	0.159	−0.63 (−2.91; 1.65)	0.567	2.81 (−0.57; 6.20)	0.101[m]
Expressing emotions, 4–20 points	0.31 (−0.91; 1.54)	0.602	0.82 (−0.65; 2.30)	0.256	0.51 (−0.52; 1.53)	0.312	−0.32 (−1.48; 0.85)	0.578	0.61 (−0.69; 1.92)	0.348[n]
Collaboration and problem-solving, 5–25 points	0.10 (−1.07; 1.27)	0.866	0.37 (−0.69; 1.43)	0.475	0.42 (−0.86; 1.70)	0.503	0.05 (−0.88; 0.98)	0.912	0.63 (−0.63; 1.90)	0.319°
Communication, 4–20 points	0.47 (−0.83; 1.78)	0.463	0.20 (−1.05; 1.45)	0.741	0.25 (−0.93; 1.44)	0.661	0.05 (−0.81; 0.92)	0.900	0.46 (−0.94; 1.87)	0.507[p]
Behavior, 4–20 points	0.24 (−0.82; 1.29)	0.649	1.43 (0.51; 2.35)	0.004*	1.01 (0.06; 1.96)	0.038*	−0.42 (−0.88; 0.04)	0.073	1.16 (0.09; 2.24)	0.034*[q]
HrQoL[e] (SF-12[f]), mean (lower; upper)										
SF-12-PCS[g], *t*-score	1.10 (−1.47; 3.68)	0.385	4.15 (0.74; 7.55)	0.020*	5.56 (1.09; 10.04)	0.018*	1.42 (−2.66; 5.49)	0.476	1.92 (−1.81; 5.65)	0.305[r]
SF-12-MCS[h], *t*-score	2.99 (0.50; 5.48)	0.021*	−2.23 (−6.97; 2.51)	0.336	−0.35 (−5.24; 4.54)	0.882	1.88 (−3.06; 6.83)	0.435	−1.60 (−6.03; 2.84)	0.471[s]
Anxiety and depression (HADS[i]), mean (lower; upper)										
HADS-A[j], 0–21 points	0.06 (−1.39; 1.51)	0.933	−1.01 (−2.62; 0.59)	0.203	−1.12 (−2.82; 0.58)	0.185	−0.11 (−1.15; 0.93)	0.834	−2.10 (−4.01; −0.20)	0.031*[t]
HADS-D[k], 0–21 points	−1.31 (−2.80; 0.19)	0.084	−0.06 (−2.42; 2.31)	0.961	−0.69 (−3.02; 1.65)	0.546	−0.63 (−2.57; 1.31)	0.504	−0.02 (−2.43; 2.39)	0.987[u]

[a]Historical control group, [b]Intervention group, [c]General Self-Efficacy Scale, [d]Iceland Expressive Family Function Questionnaire, [e]Health-related quality of life, [f]Short Form Health Survey with 12-items, [g]Physical component summary, [h]Mental component summary, [i]Hospital Anxiety and Depression Scale, [j]Hospital Anxiety and Depression Scale for Anxiety, [k]Hospital Anxiety and Depression Scale for Depression, [l]Adjusted for baseline and pain duration, [m]Adjusted for baseline, age, and number of self-reported comorbidities, [n]Adjusted for baseline, gender, and number of self-reported comorbidities. °Adjusted for baseline and number of self-reported comorbidities, [p]Adjusted for baseline, age, and number of self-reported comorbidities, [q]Adjusted for baseline and number of self-reported comorbidities, [r]Adjusted for baseline and civil status. [s]Adjusted for baseline, age, and education, [t]Adjusted for baseline, gender, and number of self-reported comorbidities, [u]Adjusted for baseline and age.

*Statistical significance.

Table 3. The Intervention Effect on Family Members.

	HCG[a]: Within-group change from baseline to post-test	*p*	IG[b]: Within-group change from baseline to post-test	*p*	IG[b]: Within-group change from baseline to follow-up	*p*	IG[b]: Within-group change from post-test to follow-up	*p*	Differences between HCG[a] and IG[b] in mean change between baseline and post-test	*p*
Primary outcome										
Self-efficacy (GSE[c]), mean (lower; upper) Total score, 10–40 points	−0.75 (−0.72; 0.21)	0.123	−0.28 (−1.86; 1.30)	0.718	0.19 (−1.52; 1.90)	0.824	0.47 (−1.06; 1.99)	0.535	0.24 (−1.36;1.84)	0.765[l]
Secondary outcomes										
Family function (ICE-EFFQ[d]), mean (lower; upper)										
Total score, 17–85 points	−0.44 (−2.09; 1.21)	0.596	1.14 (−1.24; 3.52)	0.334	1.26 (−2.23; 4.74)	0.465	0.12 (−2.93; 3.16)	0.939	1.32 (−1.39; 4.02)	0.336[m]
Expressing emotions, 4–20 points	−0.31 (−0.79; 0.18)	0.212	0.46 (−0.51; 1.42)	0.339	0.60 (−0.49; 1.70)	0.269	0.15 (−0.52; 0.81)	0.655	0.46 (−0.31; 1.22)	0.239[n]
Collaboration and problem-solving, 5–25 points	0.09 (−0.55; 0.74)	0.771	0.44 (−0.38; 1.26)	0.278	0.48 (−0.67; 1.62)	0.398	0.04 (−1.13; 1.20)	0.951	0.09 (−0.89; 1.07)	0.853[o]
Communication, 4–20 points	0.02 (−0.60; 0.63)	0.955	−0.12 (−0.84; 0.61)	0.747	−0.08 (−1.15; 1.00)	0.884	0.04 (−0.91; 0.99)	0.935	−0.14 (−1.04; 0.77)	0.767[p]
Behavior, 4–20 points	−0.24 (−0.81; 0.33)	0.401	0.36 (−0.48; 1.19)	0.388	0.25 (−0.67; 1.17)	0.581	−0.10 (−0.99; 0.79)	0.811	0.36 (−0.56; 1.27)	0.437[q]
HrQoL[e] (SF-12[f]), mean (lower; upper)										
SF-12-PCS[g], *t*-score	−0.74 (−2.84; 1.37)	0.485	−1.55 (−5.02; 1.91)	0.366	1.68 (−0.91; 4.27)	0.193	3.24 (−0.19; 6.66)	0.063	−1.08 (−4.55; 2.39)	0.536[r]
SF-12-MCS[h], *t*-score	−0.65 (−2.68; 1.39)	0.526	−1.41 (−4.16; 1.34)	0.301	−0.89 (−4.08; 2.29)	0.570	0.52 (−2.56; 3.60)	0.730	−0.59 (−3.60; 2.42)	0.698[s]
Anxiety and depression (HADS[i]), mean (lower; upper)										
HADS-A[j], 0–21 points	−0.70 (−1.58; 0.18)	0.116	−0.31 (−1.41; 0.80)	0.571	−0.19 (−1.54; 1.15)	0.772	0.12 (−0.92; 1.16)	0.819	0.30 (−0.95; 1.55)	0.634[t]
HADS-D[k], 0–21 points	−0.11 (−0.90; 0.69)	0.787	−0.04 (−1.21; 1.13)	0.947	−0.08 (−1.21; 1.05)	0.880	−0.05 (−1.33; 1.24)	0.943	0.45 (−0.61; 1.50)	0.401[u]

[a]Historical control group, [b]Intervention group, [c]General Self-Efficacy Scale, [d]Iceland Expressive Family Function Questionnaire, [e]Health-related quality of life, [f]Short Form [12-item], [g]Physical component summary, [h]Mental component summary, [i]Hospital Anxiety and Depression Scale, [j]Hospital Anxiety and Depression Scale for Anxiety, [k]Hospital Anxiety and Depression Scale for Depression. [l]Adjusted for baseline and education. [m]Adjusted for baseline.[n]Adjusted for baseline and affiliation to the patient. [o]Adjusted for baseline and education. [p]Adjusted for baseline. [q]Adjusted for baseline, education, and age. [r]Adjusted for baseline and occupation.[s]Adjusted for baseline. [t]Adjusted for baseline. [u]Adjusted for baseline, gender, and occupation.

Table 4. Differences in Baseline Variables for Patients and Family Members Who Completed and Discontinued.

	Patients					Family members				
	HCG[a]	IG[b]		HCG[a] + IG[b]		HCG[a]	IG[b]		HCG[a] + IG[b]	
		Difference	*p*	Difference	*p*		Difference	*p*	Difference	*p*
Primary outcome										
Self-efficacy (GSE[c]), mean (lower; upper)										
Total score, 10–40 points	One discontinued	−1.90 (−6.57; 2.77)	0.411	−1.44 (−5.50; 2.63)	0.482	Two discontinued	3.04 (−0.40; 6.49)	0.081	2.74 (0.06; 5.43)	0.045*
Secondary outcomes										
Family function (ICE-EFFQ[d]), mean (lower; upper)	One discontinued					Two discontinued				
Total score, 17–85 points		4.42 (−4.37; 13.20)	0.311	2.32 (−5.29; 9.92)	0.544		2.90 (−5.95; 11.74)	0.511	2.21 (−3.91; 8.34)	0.474
Expressing emotions, 4–20 points		0.05 (−1.97; 2.07)	0.960	−0.24 (−1.65; 1.16)	0.724		0.64 (−1.58; 2.85)	0.563	0.95 (−0.03; 2.93)	0.324
Collaboration and problem-solving, 5–25 points		1.54 (−1.69; 4.77)	0.336	0.70 (−1.94; 3.35)	0.596		1.07 (−1.97; 4.11)	0.478	1.09 (−1.09; 3.28)	0.324
Communication, 4–20 points		2.20 (−0.15; 4.55)	0.065	1.38 (−0.78; 3.55)	0.206		−0.19 (−2.65; 2.27)	0.874	−0.44 (−2.23; 1.36)	0.629
Behavior, 4–20 points		0.45 (−1.88; 2.77)	0.696	0.28 (−1.77; 2.32)	0.787		0.61 (−1.44; 2.66)	0.549	0.46 (−1.10; 2.02)	0.557
HrQoL[e] (SF-12[f]), mean (lower; upper)	One					Two				
SF-12-PCS[g], *t*-score	discontinued	−8.36 (−13.9; −2.83)	0.004*	−8.59 (−13.82; −3.35)	0.002*	discontinued	−2.32 (−9.17; 4.52)	0.496	−2.76 (−9.44; 3.91)	0.412
SF-12-MCS[h], *t*-score		0.23 (−7.07; 7.53)	0.950	−3.07 (−9.81; 3.68)	0.366		5.26 (−2.31; 12.84)	0.168	4.30 (−3.28; 11.88)	0.246
Anxiety and depression (HADS[i]), mean (lower; upper)	One discontinued					Two discontinued				
HADS-A[j], 0–21 points		−0.05 (−3.27; 3.17)	0.975	0.93 (−1.8; 3.65)	0.498		−1.69 (−5.33; 1.96)	0.339	−0.90 (−4.07; 2.26)	0.433
HADS-D[k], 0–21 points		0.65 (−2.69; 3.99)	0.693	2.25 (−0.50; 4.99)	0.106		−0.06 (−2.50; 2.37)	0.957	0.11 (−1.84; 2.06)	0.911

[a]Historical control group, [b]Intervention group, [c]General Self-Efficacy Scale, [d]Iceland Expressive Family Function Questionnaire, [e]Health-related quality of life, [f]Short Form [12-item], [g]Physical component summary, [h]Mental component summary, [i]Hospital Anxiety and Depression Scale, [j]Hospital Anxiety and Depression Scale for Anxiety, [k]Hospital Anxiety and Depression Scale for Depression.
*Statistical significance.

statistically significant between-group differences were detected for SF-12-MCS or PCS (Table 2).

When adjusted for baseline, gender, and number of self-reported comorbidities, the mean change of HADS-A was 2.10 (95% CI: −4.01, −0.20) lower in the IG than in the HCG (Table 2), a statistically significant difference, $p = .031$, indicating a possible, though not strong, positive effect of the intervention. In HADS-D, neither within-group change nor between-group difference was statistically significant (Table 2).

For family members' secondary outcomes, no statistically significant within-group changes nor between-group differences were found (Table 3).

Sensitivity Analyses

Normal distribution was consequently controlled for in all the *t*-tests. In some cases, where the normal distribution was deemed doubtful, sensitivity analyses using non-parametric statistics demonstrated similar significance levels as the *t*-tests.

In sensitivity analyses without imputation of missing data, patients within-group change in the HCG in SF-12 MCS was no longer statistically significant, $p = .139$. Neither their within-group change from baseline to follow-up in ICE-EFFQ BEH remained statistically significant, $p = .077$. Analyzing between-group differences without imputation did not make any difference for patients or family members.

Since many FNC series in the IG due to the COVID-19 pandemic lasted longer than expected, sensitivity analyses compared between-group mean differences for FNC series completed within or above 18 weeks, respectively. With this selection, no statistically significant between-group changes were detected for any of the patients' or family members' primary or secondary outcomes neither within nor above 18 weeks durations of the FNC series.

Table 4 displays sensitivity analyses assessing the impact of analyzing completed cases only by comparing baseline outcome variables for patients and family members who completed the series and those who discontinued. The sensitivity analyses were conducted for the HCG, the IG, and both. For the primary outcome, the mean GSE value for family members in the IG was 3.04 points (95% CI: −0.40, 6.49), $p = .081$, higher for those who completed relative to those who discontinued. For both groups in total, the mean GSE was 2.74 points higher (95% CI: 0.06, 5.43), $p = .045$, for those who completed. For the secondary outcomes, the mean value of ICE-EFFQ-communication for patients in the IG was 2.20 points higher (95% CI: −0.15, 4.55), $p = .065$, for those who completed the series relative to those who discontinued. The SF-12-PCS in the IG was 8.36 points lower (95% CI: −13.9, −2.83), $p = .004$, for patients who completed the intervention than those who discontinued. For the HCG and the IG in total, the SF-12-PCS was 8.59 points lower (95% CI: −13.82, −3.35), $p = .002$, for patients who completed the intervention than those who discontinued.

Discussion

With *p*-values above 0.05 in between-group differences in the GSE mean change, the trial's null hypothesis was not rejected, meaning that the FNC intervention with 95% probability did not have an effect on patients' and family members' self-efficacy. To the best of our knowledge, this trial is the first to examine the impact of an intervention based on the FSN framework in a CNCP population. Therefore, there is no standard of reference with which to compare. There might be several reasons to explain the lack of effect on the primary outcome. General self-efficacy is considered a universal construct (Scholz et al., 2002), which contrasts with the theoretical perception of self-efficacy as domain-specific, held by Albert Badura, the originator of the self-efficacy theory (Bandura, 1997). Thus, self-efficacy, measured by the GSE, may be too general to capture change following an FNC intervention in patients who struggle with CNCP or their family members.

For family members who completed the IG, the baseline GSE was 33.0 (Table 1), almost similar to the mean GSE of 32.9 in the average Danish population (Scholz et al., 2002), which left restricted space for improvement and may explain the marginal decrease.

The lack of effect on the primary outcome may also be ascribed to intervention fidelity. The exposure to the intervention was high (Figure 2), but it was up to the intervening nurses to determine when the specific components could be regarded as applied. According to the theoretical FSN framework behind the FNC intervention, it is essential to use the appropriate components rather than all of them (Shajani & Snell, 2019). Consequently, whether the sustained null hypothesis was caused by insufficient exposure to the FNC intervention is uncertain. What we do know is that it takes hours of experience and repeated rehearsals to become a competent intervening family nurse (Bell, 2016; Shajani & Snell, 2019). A longitudinal qualitative FANCOC-PAIN study investigating the intervening nurses' perspective illuminated an initial lack of confidence concerning their ability to meet the FNC intervention's requirements (Rønne, Esbensen, Brødsgaard, Rosenstrøm, et al., 2023). Eventually, the intervening nurses' confidence increased, but the trial was conducted while they were still in a learning process. The outcomes thus may be influenced by their limited experience. A similar explanation for the lack of effect following an FSN-based intervention was argued by Zimansky et al. (2020).

With the lower baseline mean GSE of 3.04 points (95% CI: −0.40, 6.49) displayed in Table 4 for family members who discontinued the intervention compared to those who completed the series, it may be argued that completing the FNCs was related to a high GSE. However, discontinuation of the intervention primarily emanated from the patients in whom a similar difference in the baseline mean GSE was not detected. The patients' 2.20 points higher (95% CI:

−0.15, 4.55) baseline ICE-EFFQ-communication in the IG for completers relative to discontinuers could indicate that a certain level of preexisting communication within the family unit enhanced completion. The baseline ICE-EFFQ-communication value for patients who completed the IG was 15.8 out of 20 points. For family members, it was almost identical, at 15.6 points. Since the instrument does not operate with a cutoff score, it is impossible to assess how good these scores are. In comparison, ICE-EFFQ-communication in adult Danish patients and family members during oncological treatment was 16 points (Dieperink et al., 2018). For patients with high-grade glioma brain cancer, ICE-EFFQ-communication ranged between 8.9 and 10.1, measured four times over 47 weeks, while it ranged between 9.6 and 11.7 for their caregivers (Piil et al., 2022).

The 8.36 points lower SF-12-PSC in patients who completed the intervention than those who discontinued may express a greater need for family involvement in patients with reduced physical HrQoL. However, the size of the data set allows only conjecture. With a sample size calculation recommending 22 family units in each group and only 20 IG family units completing the series, this trial was underpowered. We excluded 76% of patients assessed for eligibility for the IG, and 33% of the included family units were discontinued. The high number indicates that the analysis sample represents a selected group and should call for reflection on whether the intervention content was too demanding for a vulnerable CNCP population and their family members.

Consequently, what is the future for FNCs as an integrated part of usual multidisciplinary treatment based on this trial's results? We argue that more research is required. Though it was not strong, we did find a possible effect on the patients concerning behavioral family function and anxiety, as the positive effect on behavioral family function remained at follow-up. Since both family dysfunction and anxiety contribute to disability in patients with CNCP (Akbari et al., 2016; Edwards et al., 2016), such results are interesting. However, the conducted sensitivity analysis should give rise to caution, as when discerning between FNC series completed within or above 18 weeks. Though the sample with this selection was too small to draw any conclusions, the statistically significant between-group changes in ICE-EFFQ BEH and HADS-A did not remain. Any effect or lack thereof should thus be interpreted in light of the exceptional circumstances under which this trial was conducted.

Strengths and Limitations

Conducting the trial in a real-life setting with a quasi-experimental design had the potential for high external validity. The intervention turned out to be vigorous during unpredictable circumstances. In addition to the COVID-19 pandemic, a Danish nursing strike from June 19, 2021 to August 28, 2021, caused further delays. Moreover, due to organizational challenges at the MPC, the trial setting's patient flow and eligible patients were reduced for a more extended period. Therefore, to complete the trial within the available time, the trial setting was broadened for the IG to comprise a clinic treating patients with the specific primary pain condition of complex regional pain syndrome (CRPS) (Nicholas et al., 2019). The CRPS clinic was a satellite of the MPC and drew on the same employees in cooperation with neurologists, specialized physiotherapists, and occupational therapists. For this reason, the usual multidisciplinary treatment at the CRPS clinic and the MPC was considered to be similar. A quasi-experimental design implies reduced internal validity (Barnighausen et al., 2017), which was further lessened in this trial by the abovementioned obstacles. During the trial's extended period, inevitable changes in the trial setting diminished the groups' comparability. Together with the delayed completion of several FNC series, the results could be attributed to exposures other than the intervention. Moreover, it may have caused disproportions in who consented to participate in the trial, that eligible patients knew whether they were in the HCG or the IG from the start. Given the high numbers who discontinued the IG and the impropriety of continuing data collection after discontinuance, a per-protocol analysis was considered more appropriate than imputing data for the discontinuers (Jakobsen et al., 2017; Moher et al., 2010). Still, refining the analysis sample to completed cases only could have distorted the results (Altman, 1991).

An umbrella review by Smith et al. (2020) found that it remains unknown whether family-focused care interventions affect patients' or family members' outcomes. However, this does not mean they are not beneficial (Smith et al., 2020), and the lack of effect in the primary outcome in the present trial should be interpreted in light of this observation. The FNC intervention fulfills the criteria for complex interventions described by the Medical Research Council (Skivington et al., 2021). It is difficult to assess how the trial would have turned out without the COVID-19 interruptions. Nevertheless, preceding this trial with a feasibility study (Orsmond & Cohn, 2015), as recommended by the Medical Research Council guidance for complex interventions, could have paved the way for more appropriate outcome measures.

Implications for Practice

Despite its limitations, this quasi-experimental trial contributed to drawing attention to the benefit of an FNC intervention to support the management of CNCP in the family. In a FANCOC-PAIN study evaluating the intervention from a qualitative methodology, patients' and family members' thus also experienced the FNC intervention as helpful in managing and communicating CNCP (Rønne, Esbensen, Brødsgaard, Biering-Sørensen, et al., 2023). More research is necessary to comprehensively evaluate the benefit of FNCs to patients with CNCP and their family members.

Moreover, there is a need for examining suitable outcome measures with the sensitivity to measure change following interventions based on the FSN framework.

Conclusions

In conclusion, for the primary outcome, self-efficacy, the FNC intervention demonstrated no statistically significant within-group change or between-group differences for patients or family members. For patients, the FNC intervention may have a positive effect on patients' behavioral family function and anxiety, while no effect was detected on HrQoL. For family members, the FNC intervention did not have an effect on any of the secondary outcomes.

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