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Continuity of care interventions for preventing hospital readmission of older people with chronic diseases: A meta-analysis

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ABSTRACT

Background: Hospital readmission after discharge is a frequent, burdensome and costly event, particularly frequent in older people with multiple chronic conditions. Few literature reviews have analysed studies of continuity of care interventions to reduce readmissions of older inpatients discharged home over the short and long term.
Objective: To evaluate the effectiveness of continuity of care interventions in older people with chronic diseases in reducing short and long term hospital readmission after hospital discharge.
Design: Meta-analysis of randomized controlled trials.
Data sources: A comprehensive literature search on the databases PubMed, Medline, CINAHL and EMBASE was performed on 27 January 2019 with no language and time limits.
Review methods: RCTs on continuity of care interventions on older people discharged from hospital having hospital readmission as outcome, were included. Two reviewers independently screened the studies and assessed methodological quality using the Cochrane Risk of Bias tool. Selected outcome data were combined and pooled using a Mantel-Haenszel random-effects model.
Results: Thirty RCTs, representing 8920 patients were included. Results were stratified by time of readmissions. At 1 month from discharge, the continuity interventions were associated with lower readmission rates in 207/1595 patients in the experimental group (12.9%), versus 264/1645 patients in the control group (16%) (Relative Risk [RR], 0.84 [95% CI, 0.71-0.99]). From 1 to 3 months, readmission rates were lower in 325/1480 patients in the experimental group (21.9%), versus 455/1523 patients in the control group (29.8%) (RR 0.74 [95% CI, 0.65-0.84]). A subgroup analysis showed that this positive effect was stronger when the interventions addressed all of the continuity dimensions. After 3 months this impact became inconclusive with moderate/high statistical heterogeneity.
Conclusions: Continuity of care interventions prevent short term hospital readmission in older people with chronic diseases. However, there is inconclusive evidence about the effectiveness of continuity interventions aiming to reduce long term readmission, and it is suggested that stronger focus on it is needed.

What is already known about the topic?

- Older people with chronic conditions are associated with the highest rates of hospital readmission.
- The most-studied timeframe measuring hospital readmission is 30-day, probably due to the financial penalties introduced in Europe and US. Therefore, late hospital readmissions are understudied.
- A recent systematic review classifying interventions to reduce 30-day readmissions in older people could not identify effective any one intervention or bundle of interventions.

What this paper adds

- Continuity of care interventions prevent short term hospital readmission in older people with chronic diseases, and those

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interventions that cover all continuity dimensions are more effective.

- It is paramount that healthcare systems should be designed to support long term care of chronicity, moving beyond the 30-day standard risk readmission rate.

1. Introduction

Chronic diseases are characterized by long duration and slow progression (World Health Organization, 2014) and are often related to multimorbidity status (Lalkhen and Mash, 2015; Pengpid and Peltzer, 2017). Older people living with a chronic disease have continuing complex care needs (Coleman, 2003) that require multiple care settings. Their life-pattern is characterized by frequent transitions in health (Naylor, 2012), high rates of hospital readmission (Berry et al., 2018) and involvement of patients, families and several healthcare providers in their care over a long period of time (Naylor, 2012). Chronic diseases can decrease quality of life and productivity and, if they are not effectively managed, result in acute and long-term complications requiring expensive hospitalizations and readmissions (Dye et al., 2018).

Effective management of chronicity includes continuity of care interventions with the goal of connecting and coordinating care between patients and providers across time and settings (Russell et al., 2011; van Servellen et al., 2006; Yang et al., 2017). Continuity of care occurs when healthcare events are experienced by patients as coherent, connected and consistent with their complex care needs (Haggerty et al., 2003). It is composed of three dimensions of continuity: *relational* (a patient-provider relationship over time), *informational* (the effective transfer and use of patients' past and current personal information) and *management* (consistent and timely coordination of care and services) (Haggerty et al., 2003). These elements are closely interrelated and should be all integrated by effective healthcare organizations (Guthrie et al., 2008). Moreover, two "core elements" distinguish continuity of care from other attributes of care: a focus on the patients' experience and the timeframe.

Most of the efforts spent on ensuring continuity of care aim at the reduction of hospital readmissions (Pacho et al., 2017), which are a common burden to healthcare systems (Gerhardt et al., 2013; Unruh et al., 2017), and undesirable events for patients (Kripalani et al., 2014). Older people perceived readmission to hospital as a challenge and a negative experience; they also felt that their existential, emotional and psychological wellbeing was not addressed by healthcare professionals (Blakey et al., 2017).

In literature, the most-studied timeframe measuring hospital readmission is 30-day, (Kristensen et al., 2015) probably due to the financial penalties introduced in Europe and US that forced hospitals to reduce early readmissions (Gupta and Fonarow, 2018) through pre and post-discharge continuity interventions. A number of publications exist on continuity of care interventions to reduce hospital readmission in adult patients but few reviews were conducted of studies on older people with chronic diseases. A systematic review aimed at classifying interventions to reduce 30-day readmissions in older people could not identify an intervention or bundle of interventions that reliably reduced readmissions (Hansen et al., 2011). Indeed, the effectiveness of continuity of care interventions in reducing hospital readmission in older people, in particular in the long-term, is still understudied. To date, the only metanalysis on the effectiveness of continuity of care intervention in the short and long term was conducted on adult patients with Chronic Obstructive Pulmonary Disease discharged home, with conflicting results (Yang et al., 2017). Therefore, the evidence on continuity of care interventions that effectively reduce both early and long term hospital readmission in older people with chronic diseases is sparse.

This systematic review of randomized controlled trials (RCTs) aims to evaluate the effectiveness of continuity of care interventions in older people with chronic diseases in reducing short and long term hospital readmission after hospital discharge.

2. Method

This review was reported in accordance with PRISMA statement guidance (Liberati et al., 2009). The protocol was previously registered on PROSPERO, registration number CRD42016050755. Preliminary searches of main databases could not find any existing or ongoing systematic reviews with this aim.

2.1. Eligibility criteria and search strategy

This review included only RCT with following inclusion criteria:

Types of participants: older patients ($\geq$ 65 years) diagnosed with one or more chronic diseases (World Health Organization, 2014), who were discharged home from hospital. Studies on cancer or psychiatric patients were excluded due to the particular illness trajectories characterizing those patients.

Types of intervention: continuity of care interventions provided by any healthcare professional during and after hospital discharge. Continuity of care interventions are defined as those focusing on the connection and coordination between patients and providers across time and settings and classified in informational, management, and relational continuity interventions (Reid et al., 2002). To be included, the interventions had to address at least one type of continuity (informational, management or relational) (Further details in Table 1).

Table 1
Characteristics of continuity of care dimensions.

Continuity of care dimensions (Reid et al., 2002)
Relational continuity Relational continuity refers to an established relationship between patient and provider that extends across illnesses over time. An ongoing patient-provider relationship helps bridge discontinuous events and provides patients and caregivers with a sense of predictability and coherence. Relational continuity interventions usually refer to the strength of interpersonal relationships including the level of communication, comfort, trust and belief.
Informational continuity Informational continuity is the transfer and use of information from previous events and conditions to plan appropriate interventions. The availability and use of data from prior events are a prerequisite for coordination of care, and accumulated knowledge is important for bridging separate care events and ensuring that services are responsive to patients' needs. Informational continuity interventions are related to the availability of documentation and to the comprehensiveness of information transfer between providers and settings.
Management continuity Management continuity is achieved when interventions are delivered in a complementary and timely manner. When care is long term, the ability to provide consistent, predictable care is pivotal and care needs to be flexible enough to respond to changing patient health status and needs. Outreach and on-going monitoring are important to adapt the care strategy to the changing needs of the patients with a focus on individualized care plans and to increase patients'/caregivers' self-care.

Specifically, if the care was provided longitudinally with an ongoing therapeutic relationship with one or more providers who connect care over time, the interventions were considered as relational continuity. For example, the presence of a transitional care nurse who follows patients from hospital into their homes and guarantees the liaison with healthcare providers and the primary care hub.

If the information about patient's health was available and transferred from one provider to another throughout the follow-up period, the interventions were considered as informational continuity. For example, the use of interventions to record information such as electronic record charts, referral forms, and written discharge plans. As well as strategies to empower patients in their care through informational booklets or medication reconciliation.

When the care was provided with tailored and shared interventions to ensure consistency during treatment, the interventions were considered as management continuity. For example, the presence of a case manager who plays a vital role in patients/caregivers training and coaching with the aim to enhance their self-confidence in monitoring and managing the symptoms.

Since continuity of care is a result of the interconnection of all three dimensions, the more the interventions address different dimensions of continuity, the greater is the likelihood of the patients' experiencing continuity of care (Reid et al., 2002).

Types of outcome: all-cause hospital readmissions measured as the number of patients readmitted in both experimental and control groups during the follow up of 1 month, 1< months ≤ 3; 3< month ≤ 6, and 6< month ≤ 12 from discharge.

To enhance homogeneity, only studies in which the duration of intervention was as long as the readmission timeframe considered were included. For example, the studies included in the results of "readmission at 1 month" evaluated readmission at 1 month and interventions carried out in the course of 1 month; the studies included in the results of "readmission 1< months ≤ 3" evaluated readmission from 1 up to 3 months and interventions carried out in the course of up to three months, and so on.

A comprehensive literature search on the databases PubMed, Medline, CINAHL and EMBASE was performed on 27 January 2019 with no language and time limits. Medical subject headings and free-terms were searched for the following keywords: chronic disease, aged, continuity of patient care, hospital readmission (Appendix 1). Search strategies were checked by three reviewers (GF, DD, MP).

2.2. Study selection and data collection

Study screening was conducted independently by two reviewers (GF, DD). First, titles and abstracts and then full-texts selected from the first round were reviewed based on the inclusion criteria. To maximize search sensitivity a snowball method was used and the reference lists of the full-texts included were screened. Conflicts regarding study inclusion were resolved by mutual agreement between reviewers. The data from the full-texts selected were extracted independently by two authors (DA, AO) and checked by a third author (GF). Extracted data included first author, publication year, country, sample size, patient disease, interventions, follow-up time, type of continuity dimension, and principal healthcare provider involved in the intervention.

2.3. Quality assessment

Two reviewers independently evaluated the methodological quality and reliability of the findings through the risk of bias tool (Higgins et al., 2011). Study quality was assessed with the following criteria: selection, performance, detection, attrition, reporting and other biases. Each criterion was evaluated assigning zero for low risk, one point for unclear, and two points for high risk of bias. The potential total score ranged 0–14, in which a low score indicated higher quality level, and a high score indicated lower quality (Massimi et al., 2017). Based on this score, the studies were classified in three levels: low (> 3), moderate (2–3) and high (0–1) quality. Only moderate and high quality studies were included in review, to limit heterogeneity and improve the reliability of the study.

2.4. Definition of outcome

The primary outcome was the effectiveness of continuity of care interventions in reducing hospital readmissions of older patients with chronic diseases in the time sections of 1 month; 1< months ≤ 3; 3< months ≤ 6, and 6< months ≤ 12 months from discharge.

2.5. Data synthesis and analysis

Double data entry was performed by two reviewers (GF, DD). The number of patients readmitted in each group were reported and combined for the analysis. A meta-analysis was conducted using Review Manager software version 5.3 to pool data at different outcomes. For each study, we computed the relative risk (RR) of readmission at different outcomes. Pooled risk ratios and 95% of confidence intervals (CI) were computed by means of a Mantel-Haenszel random-effects modeltest (Mantel and Haenszel, 1959). Statistical heterogeneity was assessed using the standard chi-square (Cochran, 1954) and I-square with a value of greater than 50% indicating substantial heterogeneity (Higgins et al., 2003). Egger's test was used to detect funnel plot asymmetry (Higgins, 2011) and to assess potential publication bias. Subgroup analyses were planned on the time of follow-up (short and long term). Subgroup analyses were conducted to explore whether readmission risk at different time sections varied according to the number of continuity dimensions (three versus any) addressed by the interventions.

A post-hoc sensitivity analysis was conducted excluding those studies in which the randomization process was not clearly reported, multi-component continuity interventions were not employed, and the readmission rate was considered as a secondary outcome.

3. Results

The selection process is illustrated in Fig. 1. The search strategy yielded 854 articles. After duplicate removal and titles, abstracts and full-texts review, 36 studies were evaluated for methodological quality, 30 of which resulted eligible for the review and metanalysis.

3.1. Study and patient characteristics

A total of 8920 older patients discharged from hospital to home were included. All the studies were published in English in peer-reviewed journals from 1993 to 2018, and were mostly conducted in the USA (n = 10), China (n = 5), and Australia (n = 3). Patients were affected by chronic heart failure in 16 studies (53%), chronic obstructive pulmonary disease in 3 studies (10%), chronic obstructive pulmonary disease plus chronic heart failure in 2 studies (7%) and chronic lung disease in 1 study (3%). The remaining 8 studies (27%) coded patients' diseases under the broader classification of multi chronic disease (Table 2).

3.2. Intervention characteristics

The number of interventions carried out per each study ranged from 1 to 6. Eighteen different types of interventions were identified among which home visits (N = 17), telephone follow-up

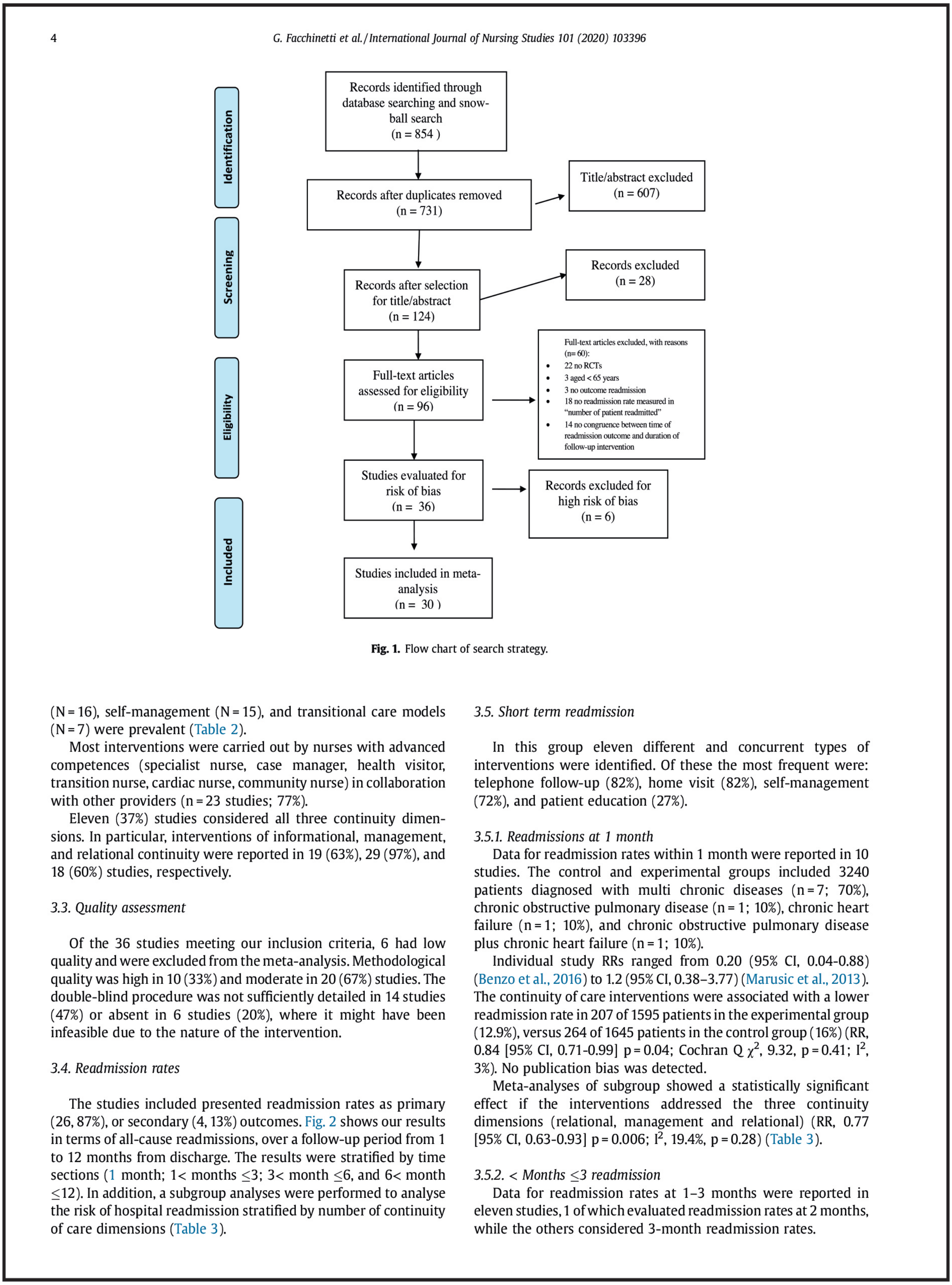


Fig. 1. Flow chart of search strategy.

(N = 16), self-management (N = 15), and transitional care models (N = 7) were prevalent (Table 2).

Most interventions were carried out by nurses with advanced competences (specialist nurse, case manager, health visitor, transition nurse, cardiac nurse, community nurse) in collaboration with other providers (n = 23 studies; 77%).

Eleven (37%) studies considered all three continuity dimensions. In particular, interventions of informational, management, and relational continuity were reported in 19 (63%), 29 (97%), and 18 (60%) studies, respectively.

3.3. Quality assessment

Of the 36 studies meeting our inclusion criteria, 6 had low quality and were excluded from the meta-analysis. Methodological quality was high in 10 (33%) and moderate in 20 (67%) studies. The double-blind procedure was not sufficiently detailed in 14 studies (47%) or absent in 6 studies (20%), where it might have been infeasible due to the nature of the intervention.

3.4. Readmission rates

The studies included presented readmission rates as primary (26, 87%), or secondary (4, 13%) outcomes. Fig. 2 shows our results in terms of all-cause readmissions, over a follow-up period from 1 to 12 months from discharge. The results were stratified by time sections (1 month; $1<$ months ≤ 3; $3<$ month ≤ 6, and $6<$ month ≤ 12). In addition, a subgroup analyses were performed to analyse the risk of hospital readmission stratified by number of continuity of care dimensions (Table 3).

3.5. Short term readmission

In this group eleven different and concurrent types of interventions were identified. Of these the most frequent were: telephone follow-up (82%), home visit (82%), self-management (72%), and patient education (27%).

3.5.1. Readmissions at 1 month

Data for readmission rates within 1 month were reported in 10 studies. The control and experimental groups included 3240 patients diagnosed with multi chronic diseases (n = 7; 70%), chronic obstructive pulmonary disease (n = 1; 10%), chronic heart failure (n = 1; 10%), and chronic obstructive pulmonary disease plus chronic heart failure (n = 1; 10%).

Individual study RRs ranged from 0.20 (95% CI, 0.04-0.88) (Benzo et al., 2016) to 1.2 (95% CI, 0.38–3.77) (Marusic et al., 2013). The continuity of care interventions were associated with a lower readmission rate in 207 of 1595 patients in the experimental group (12.9%), versus 264 of 1645 patients in the control group (16%) (RR, 0.84 [95% CI, 0.71-0.99] p = 0.04; Cochran Q χ^2, 9.32, p = 0.41; I^2, 3%). No publication bias was detected.

Meta-analyses of subgroup showed a statistically significant effect if the interventions addressed the three continuity dimensions (relational, management and relational) (RR, 0.77 [95% CI, 0.63-0.93] p = 0.006; I^2, 19.4%, p = 0.28) (Table 3).

3.5.2. < Months ≤ 3 readmission

Data for readmission rates at 1–3 months were reported in eleven studies, 1 of which evaluated readmission rates at 2 months, while the others considered 3-month readmission rates.

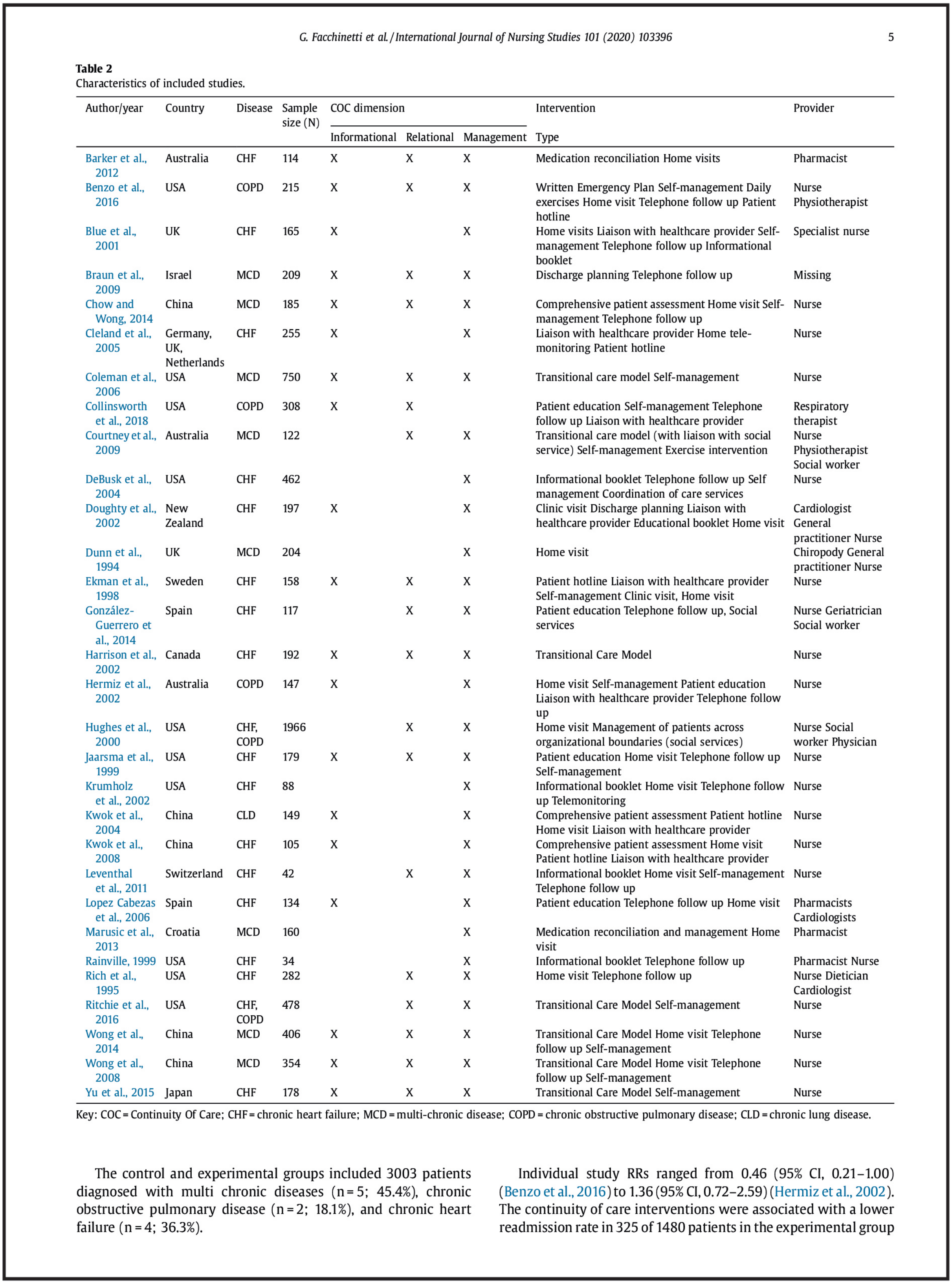


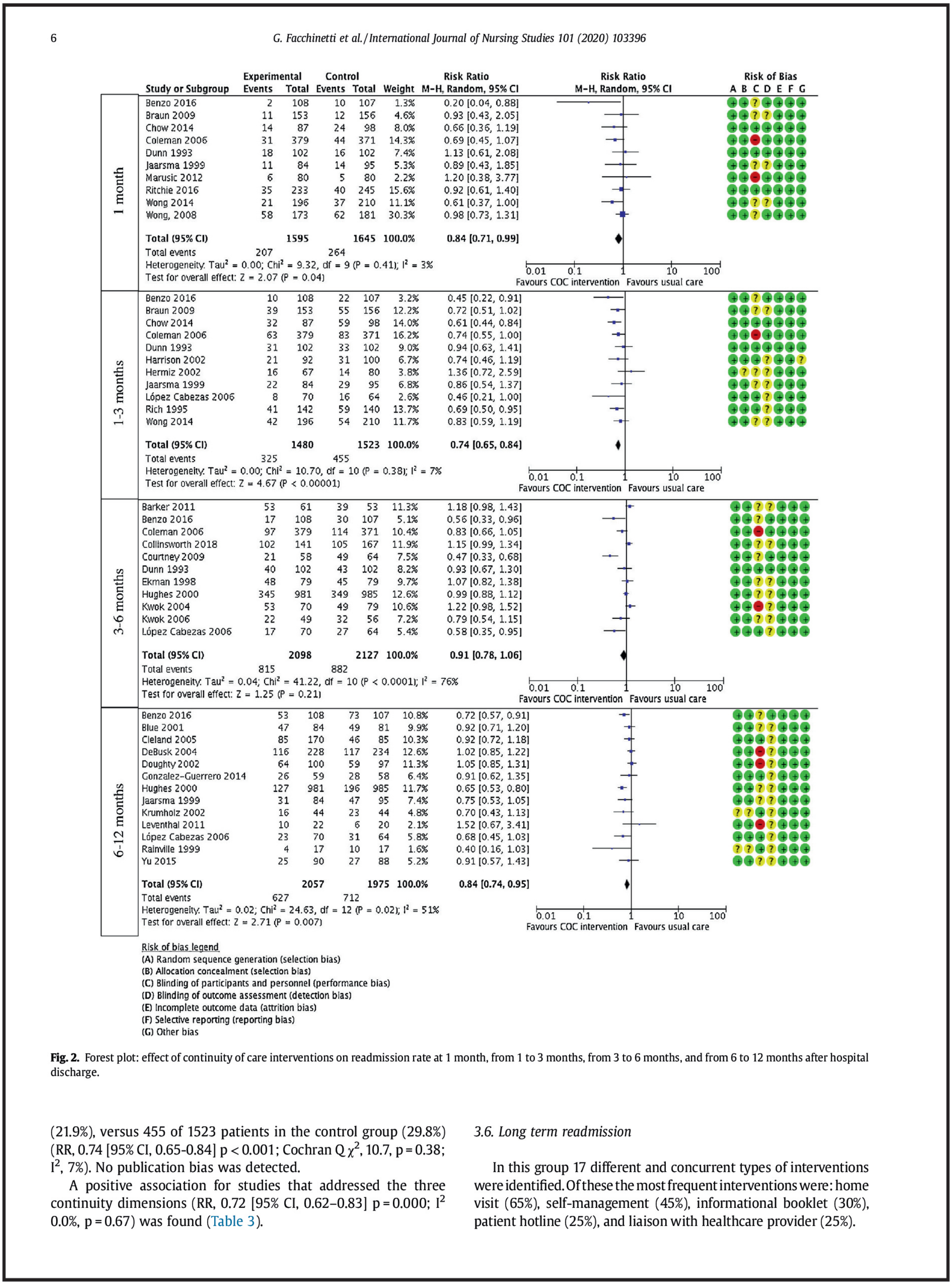
Table 2
Characteristics of included studies.

Author/year	Country	Disease	Sample size (N)	COC dimension			Intervention	Provider
				Informational	Relational	Management	Type	
Barker et al., 2012	Australia	CHF	114	X	X	X	Medication reconciliation Home visits	Pharmacist
Benzo et al., 2016	USA	COPD	215	X	X	X	Written Emergency Plan Self-management Daily exercises Home visit Telephone follow up Patient hotline	Nurse Physiotherapist
Blue et al., 2001	UK	CHF	165	X		X	Home visits Liaison with healthcare provider Self-management Telephone follow up Informational booklet	Specialist nurse
Braun et al., 2009	Israel	MCD	209	X	X	X	Discharge planning Telephone follow up	Missing
Chow and Wong, 2014	China	MCD	185	X	X	X	Comprehensive patient assessment Home visit Self-management Telephone follow up	Nurse
Cleland et al., 2005	Germany, UK, Netherlands	CHF	255	X		X	Liaison with healthcare provider Home tele-monitoring Patient hotline	Nurse
Coleman et al., 2006	USA	MCD	750	X	X	X	Transitional care model Self-management	Nurse
Collinsworth et al., 2018	USA	COPD	308	X	X		Patient education Self-management Telephone follow up Liaison with healthcare provider	Respiratory therapist
Courtney et al., 2009	Australia	MCD	122		X	X	Transitional care model (with liaison with social service) Self-management Exercise intervention	Nurse Physiotherapist Social worker
DeBusk et al., 2004	USA	CHF	462			X	Informational booklet Telephone follow up Self management Coordination of care services	Nurse
Doughty et al., 2002	New Zealand	CHF	197	X		X	Clinic visit Discharge planning Liaison with healthcare provider Educational booklet Home visit	Cardiologist General practitioner Nurse
Dunn et al., 1994	UK	MCD	204			X	Home visit	Chiropody General practitioner Nurse
Ekman et al., 1998	Sweden	CHF	158	X	X	X	Patient hotline Liaison with healthcare provider Self-management Clinic visit, Home visit	Nurse
González-Guerrero et al., 2014	Spain	CHF	117		X	X	Patient education Telephone follow up, Social services	Nurse Geriatrician Social worker
Harrison et al., 2002	Canada	CHF	192	X	X	X	Transitional Care Model	Nurse
Hermiz et al., 2002	Australia	COPD	147	X		X	Home visit Self-management Patient education Liaison with healthcare provider Telephone follow up	Nurse
Hughes et al., 2000	USA	CHF, COPD	1966		X	X	Home visit Management of patients across organizational boundaries (social services)	Nurse Social worker Physician
Jaarsma et al., 1999	USA	CHF	179	X	X	X	Patient education Home visit Telephone follow up Self-management	Nurse
Krumholz et al., 2002	USA	CHF	88			X	Informational booklet Home visit Telephone follow up Telemonitoring	Nurse
Kwok et al., 2004	China	CLD	149	X		X	Comprehensive patient assessment Patient hotline Home visit Liaison with healthcare provider	Nurse
Kwok et al., 2008	China	CHF	105	X		X	Comprehensive patient assessment Home visit Patient hotline Liaison with healthcare provider	Nurse
Leventhal et al., 2011	Switzerland	CHF	42		X	X	Informational booklet Home visit Self-management Telephone follow up	Nurse
Lopez Cabezas et al., 2006	Spain	CHF	134	X		X	Patient education Telephone follow up Home visit	Pharmacists Cardiologists
Marusic et al., 2013	Croatia	MCD	160			X	Medication reconciliation and management Home visit	Pharmacist
Rainville, 1999	USA	CHF	34			X	Informational booklet Telephone follow up	Pharmacist Nurse
Rich et al., 1995	USA	CHF	282		X	X	Home visit Telephone follow up	Nurse Dietician Cardiologist
Ritchie et al., 2016	USA	CHF, COPD	478		X	X	Transitional Care Model Self-management	Nurse
Wong et al., 2014	China	MCD	406	X	X	X	Transitional Care Model Home visit Telephone follow up Self-management	Nurse
Wong et al., 2008	China	MCD	354	X	X	X	Transitional Care Model Home visit Telephone follow up Self-management	Nurse
Yu et al., 2015	Japan	CHF	178	X	X	X	Transitional Care Model Self-management	Nurse

Key: COC = Continuity Of Care; CHF = chronic heart failure; MCD = multi-chronic disease; COPD = chronic obstructive pulmonary disease; CLD = chronic lung disease.

The control and experimental groups included 3003 patients diagnosed with multi chronic diseases (n = 5; 45.4%), chronic obstructive pulmonary disease (n = 2; 18.1%), and chronic heart failure (n = 4; 36.3%).

Individual study RRs ranged from 0.46 (95% CI, 0.21–1.00) (Benzo et al., 2016) to 1.36 (95% CI, 0.72–2.59) (Hermiz et al., 2002). The continuity of care interventions were associated with a lower readmission rate in 325 of 1480 patients in the experimental group



1 month

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI	A	B	C	D	E	F	G
Benzo 2016	2	108	10	107	1.3%	0.20 [0.04, 0.88]	+	+	?	+	+	+	+
Braun 2009	11	153	12	156	4.6%	0.93 [0.43, 2.05]	+	+	?	?	+	+	+
Chow 2014	14	87	24	98	8.0%	0.66 [0.36, 1.19]	+	+	+	+	+	+	+
Coleman 2006	31	379	44	371	14.3%	0.69 [0.45, 1.07]	+	+	−	+	+	+	+
Dunn 1993	18	102	16	102	7.4%	1.13 [0.61, 2.08]	+	+	+	+	+	+	+
Jaarsma 1999	11	84	14	95	5.3%	0.89 [0.43, 1.85]	+	+	?	?	+	+	+
Marusic 2012	6	80	5	80	2.2%	1.20 [0.38, 3.77]	+	+	−	+	+	+	+
Ritchie 2016	35	233	40	245	15.6%	0.92 [0.61, 1.40]	+	+	+	+	+	+	+
Wong 2014	21	196	37	210	11.1%	0.61 [0.37, 1.00]	+	+	?	?	+	+	+
Wong, 2008	58	173	62	181	30.3%	0.98 [0.73, 1.31]	+	+	?	+	+	+	+
Total (95% CI)		**1595**		**1645**	**100.0%**	**0.84 [0.71, 0.99]**							
Total events	207		264										

Heterogeneity: Tau² = 0.00; Chi² = 9.32, df = 9 (P = 0.41); I² = 3%
Test for overall effect: Z = 2.07 (P = 0.04)

1-3 months

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI	A	B	C	D	E	F	G
Benzo 2016	10	108	22	107	3.2%	0.45 [0.22, 0.91]	+	+	?	+	+	+	+
Braun 2009	39	153	55	156	12.2%	0.72 [0.51, 1.02]	+	+	?	?	+	+	+
Chow 2014	32	87	59	98	14.0%	0.61 [0.44, 0.84]	+	+	+	+	+	+	+
Coleman 2006	63	379	83	371	16.2%	0.74 [0.55, 1.00]	+	+	−	+	+	+	+
Dunn 1993	31	102	33	102	9.0%	0.94 [0.63, 1.41]	+	+	+	+	+	+	+
Harrison 2002	21	92	31	100	6.7%	0.74 [0.46, 1.19]	+	+	+	?	+	+	?
Hermiz 2002	16	67	14	80	3.8%	1.36 [0.72, 2.59]	+	?	?	?	+	+	+
Jaarsma 1999	22	84	29	95	6.8%	0.86 [0.54, 1.37]	+	+	?	?	+	+	+
López Cabezas 2006	8	70	16	64	2.6%	0.46 [0.21, 1.00]	+	+	+	?	+	+	+
Rich 1995	41	142	59	140	13.7%	0.69 [0.50, 0.95]	+	+	+	?	+	+	+
Wong 2014	42	196	54	210	11.7%	0.83 [0.59, 1.19]	+	+	?	?	+	+	+
Total (95% CI)		**1480**		**1523**	**100.0%**	**0.74 [0.65, 0.84]**							
Total events	325		455										

Heterogeneity: Tau² = 0.00; Chi² = 10.70, df = 10 (P = 0.38); I² = 7%
Test for overall effect: Z = 4.67 (P < 0.00001)

3-6 months

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI	A	B	C	D	E	F	G
Barker 2011	53	61	39	53	11.3%	1.18 [0.98, 1.43]	+	+	?	?	+	+	+
Benzo 2016	17	108	30	107	5.1%	0.56 [0.33, 0.96]	+	+	?	+	+	+	+
Coleman 2006	97	379	114	371	10.4%	0.83 [0.66, 1.05]	+	+	−	+	+	+	+
Collinsworth 2018	102	141	105	167	11.9%	1.15 [0.99, 1.34]	+	+	?	?	+	+	+
Courtney 2009	21	58	49	64	7.5%	0.47 [0.33, 0.68]	+	+	?	+	+	+	+
Dunn 1993	40	102	43	102	8.2%	0.93 [0.67, 1.30]	+	+	+	+	+	+	+
Ekman 1998	48	79	45	79	9.7%	1.07 [0.82, 1.38]	+	+	?	?	+	+	+
Hughes 2000	345	981	349	985	12.6%	0.99 [0.88, 1.12]	+	+	?	?	+	+	+
Kwok 2004	53	70	49	79	10.6%	1.22 [0.98, 1.52]	+	+	−	?	+	+	+
Kwok 2006	22	49	32	56	7.2%	0.79 [0.54, 1.15]	+	+	?	?	+	+	+
López Cabezas 2006	17	70	27	64	5.4%	0.58 [0.35, 0.95]	+	+	+	?	+	+	+
Total (95% CI)		**2098**		**2127**	**100.0%**	**0.91 [0.78, 1.06]**							
Total events	815		882										

Heterogeneity: Tau² = 0.04; Chi² = 41.22, df = 10 (P < 0.0001); I² = 76%
Test for overall effect: Z = 1.25 (P = 0.21)

6-12 months

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI	A	B	C	D	E	F	G
Benzo 2016	53	108	73	107	10.8%	0.72 [0.57, 0.91]	+	+	?	+	+	+	+
Blue 2001	47	84	49	81	9.9%	0.92 [0.71, 1.20]	+	+	?	?	+	+	+
Cleland 2005	85	170	46	85	10.3%	0.92 [0.72, 1.18]	+	+	+	?	+	+	+
DeBusk 2004	116	228	117	234	12.6%	1.02 [0.85, 1.22]	+	+	−	?	+	+	+
Doughty 2002	64	100	59	97	11.3%	1.05 [0.85, 1.31]	+	+	−	?	+	+	+
Gonzalez-Guerrero 2014	26	59	28	58	6.4%	0.91 [0.62, 1.35]	+	+	+	?	+	+	+
Hughes 2000	127	981	196	985	11.7%	0.65 [0.53, 0.80]	+	+	?	?	+	+	+
Jaarsma 1999	31	84	47	95	7.4%	0.75 [0.53, 1.05]	+	+	?	?	+	+	+
Krumholz 2002	16	44	23	44	4.8%	0.70 [0.43, 1.13]	?	?	+	?	+	+	+
Leventhal 2011	10	22	6	20	2.1%	1.52 [0.67, 3.41]	+	+	−	?	+	+	+
López Cabezas 2006	23	70	31	64	5.8%	0.68 [0.45, 1.03]	+	+	+	?	+	+	+
Rainville 1999	4	17	10	17	1.6%	0.40 [0.16, 1.03]	?	?	+	?	+	+	+
Yu 2015	25	90	27	88	5.2%	0.91 [0.57, 1.43]	+	+	?	?	+	+	+
Total (95% CI)		**2057**		**1975**	**100.0%**	**0.84 [0.74, 0.95]**							
Total events	627		712										

Heterogeneity: Tau² = 0.02; Chi² = 24.63, df = 12 (P = 0.02); I² = 51%
Test for overall effect: Z = 2.71 (P = 0.007)

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Fig. 2. Forest plot: effect of continuity of care interventions on readmission rate at 1 month, from 1 to 3 months, from 3 to 6 months, and from 6 to 12 months after hospital discharge.

(21.9%), versus 455 of 1523 patients in the control group (29.8%) (RR, 0.74 [95% CI, 0.65-0.84] $p < 0.001$; Cochran Q χ^2, 10.7, $p = 0.38$; I^2, 7%). No publication bias was detected.

A positive association for studies that addressed the three continuity dimensions (RR, 0.72 [95% CI, 0.62–0.83] $p = 0.000$; I^2 0.0%, $p = 0.67$) was found (Table 3).

3.6. Long term readmission

In this group 17 different and concurrent types of interventions were identified. Of these the most frequent interventions were: home visit (65%), self-management (45%), informational booklet (30%), patient hotline (25%), and liaison with healthcare provider (25%).

Table 3
Meta-analysis of the risk of hospital readmission stratified by continuity of care dimensions.

SUBGROUPS	*Readmission*	*Studies (N)*	*RR (95% CI)*	I^2*(%)*	p^*
ALL CONTINUITY OF CARE DIMENSIONS	1 month	7	0.77 (0.63-0.93)	19.40	0.28
	1< months ≤3	7	0.72 (0.62-0.83)	0.00	0.67
	3< month ≤6	4	0.91(0.79-1.04)	76.5	0.00
	6< month ≤12	3	0.76 (0.64-0.91)	0.00	0.67
ANY CONTINUITY OF CARE DIMENSIONS	1 month	3	1.00 (0.72-1.39)	0.00	0.82
	1< months ≤3	4	0.79 (0.63-0.99)	51.2	0.10
	3< month ≤6	6	0.93 (0.85-1.02)	79.5	0.00
	6< month ≤12	10	0.84 (0.76-0.92)	58.7	0.01

Key: * *p* value for heterogeneity.

3.6.1. < Month ≤6 readmission

Eleven studies evaluated 6-month readmission rates. The control and experimental groups included 4225 patients diagnosed with multi chronic diseases ($n = 3$; 27%), chronic obstructive pulmonary disease ($n = 2$; 18%), chronic heart failure ($n = 4$; 36%), chronic obstructive pulmonary disease plus chronic heart failure ($n = 1$; 9%) and chronic lung disease ($n = 1$; 9%).

Individual study RRs ranged from 0.47 (95% CI, 0.33-0.68) (Courtney et al., 2009) to 1.22 (95% CI, 0.98–1.52) (Kwok et al., 2004). There appeared to be a reduction in hospital readmission with continuity interventions (RR, 0.91 [95% CI, 0.78–1.06]; $p = 0.21$). However, both approaches for heterogeneity indicated considerable heterogeneity ($Q\chi^2$ 41.22, $p < 0.001$; $I^2 = 76\%$) for this outcome, with the presence of publication bias on the test for asymmetry of the funnel plot, and a borderline small size effect ($p = 0.075$).

Null association with high heterogeneity was noted for studies that addressed either three continuity dimensions (RR, 0.91 [95% CI, 0.79–1.04] $p = 0.1$; I^2 76.5%, $p = 0.005$) or any continuity dimension (RR, 0.93 [95% CI, 0.85–1.02] $p = 0.12$; I^2 79.5%, $p = 0.000$) (Table 3).

3.6.2. < Month ≤12 months readmission

A total of 13 studies are included in this timeframe, 1 of which considered 8 months, 3 studies considered 9 months, while the others considered 12 months readmission rate.

The control and experimental groups included 4032 patients diagnosed with chronic obstructive pulmonary disease ($n = 1$; 7.69%), chronic heart failure ($n = 11$; 84.6%), and chronic obstructive pulmonary disease plus chronic heart failure ($n = 1$; 7.69%).

Individual study RRs ranged from 0.40 (95% CI, 0.16–1.03) (Rainville, 1999) to 1.52 (95% CI, 0.67–3.41) (Leventhal et al., 2011). Although the pooled data on hospital readmission are in favour of intervention (RR, 0.84 [95% CI, 0.74-0.95]), the Cochran Q χ^2 of 24.63 ($p = 0.02$), and the I^2 of 51% suggested the presence of a moderate study variability. Moreover, publication bias was detected among studies ($p = 0.49$).

We observed a positive association for studies that addressed three continuity dimensions (RR, 0.76 [95% CI, 0.64–0.91] $p = 0.003$; I^2 0.0%, $p = 0.67$) (Table 3), but an important heterogeneity between studies (RR, 0.84 [95% CI, 0.76–0.92] $p = 0.000$; I^2 58.7%, $p = 0.01$) that addressed any continuity dimensions precludes any conclusion on the effectiveness of such interventions.

3.7. Sensitivity analysis

The recalculation of the pooled estimates RR did not significantly alter the effect of the continuity interventions on all-cause readmission.

4. Discussion

To our knowledge, this is the first systematic review and metanalysis specifically evaluating the effectiveness of continuity of care interventions in older people with chronic diseases in reducing hospital readmission in the short and long term after hospital discharge.

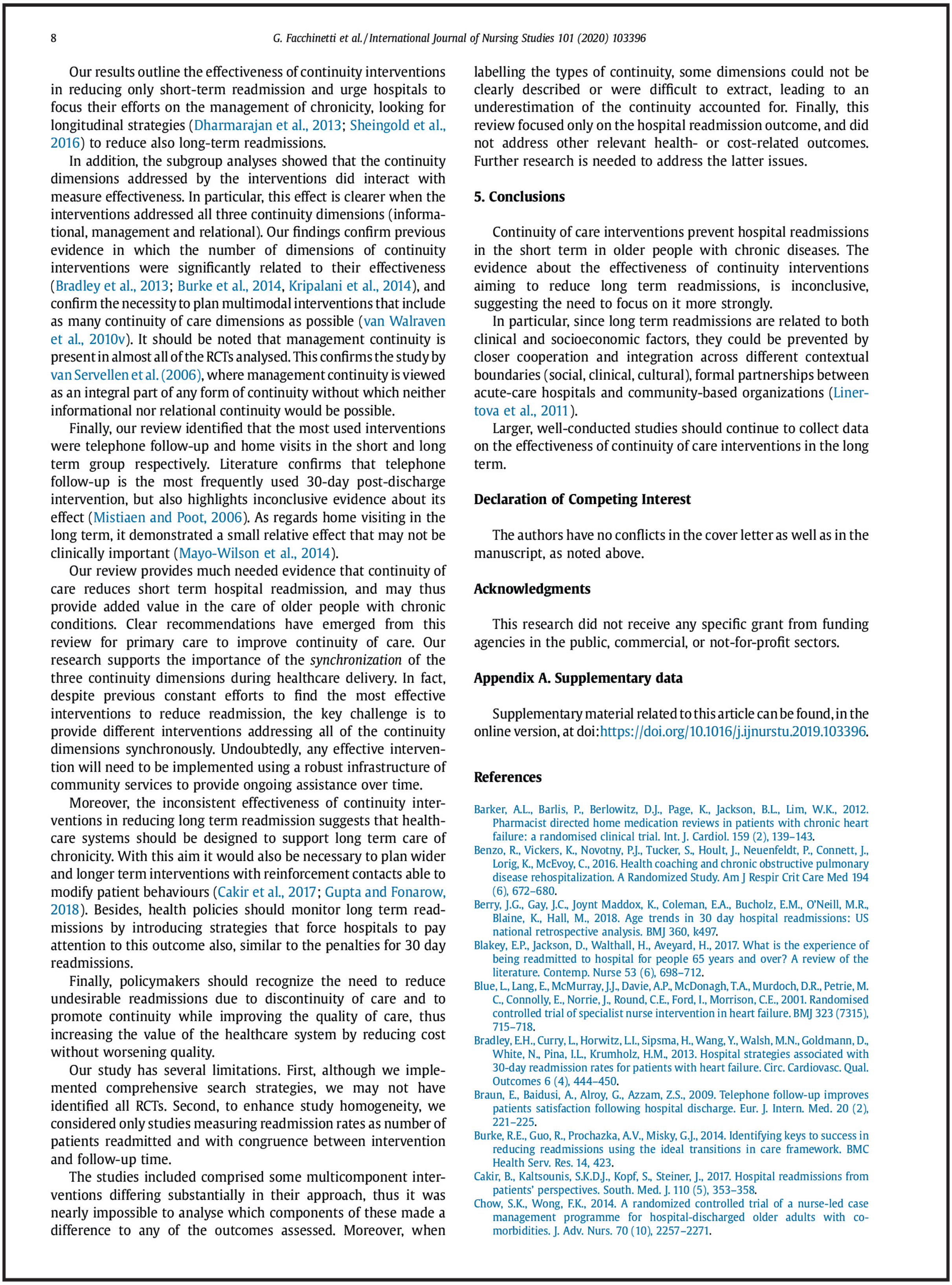
Continuity of care interventions in the short term are associated with lower readmission rates. In the long term from discharge the impact on readmission rates becomes inconclusive, with high/moderate statistical heterogeneity ($I^2 = 76\%$, 51%). This means that as the follow-up time becomes longer, the effect of continuity of care interventions becomes unclear.

Although a recent Cochrane review did not focus specifically on continuity interventions in chronically ill older people, but on discharge planning elements in a broader population, their results showing a lower readmission rate at three months from discharge are consistent with our findings (Goncalves-Bradley et al., 2016).

A meta-analysis of 42 RCTs targeting 30-day readmissions (Leppin et al., 2014), found a pooled risk ratio of 0.82 (95% CI, 0.73-0.91) that is very similar to our results at the same time frame (RR, 0.84 [95% CI, 0.71-0.99]). However, while Leppin et al. (2014) failed to find an interaction between their results and the age of participants, our analysis shows the consistent and beneficial effect of continuity of care intervention in reducing 30-day readmissions in older people. This finding is important for clinical practice because historically about a quarter of older people are readmitted to hospital within the first three months of discharge (Nuckols et al., 2017).

No clear evidence of continuity of care interventions on hospital readmissions in the long term was shown, mainly due to heterogeneity of the studies that biased the analyses. This is consistent with a study on the effectiveness of strategies to promote safe transition of older people that showed how multi-competent continuity interventions were effective in reducing readmissions within 3 months, but found no evidence for their benefit in the longer term (Mansah et al., 2009).

Older people with chronic diseases usually require frequent hospitalization to manage the exacerbations of their chronic disorders. When they enter the hospital setting the focus of care shifts from chronic to acute management to stabilize it (Vashi et al., 2013). As a consequence, early readmissions are attributed to the hospital's insufficient recognition of care needs, closely connected with the underlying diseases that have determined the admission, and to a poor discharge process (Zuckerman et al., 2016). Conversely, readmissions after a longer time are more likely to be due to events related to patient self-management, outpatient care, socio-economic issues, and community resources, rather than to the underlying disease (Kripalani et al., 2014).



Our results outline the effectiveness of continuity interventions in reducing only short-term readmission and urge hospitals to focus their efforts on the management of chronicity, looking for longitudinal strategies (Dharmarajan et al., 2013; Sheingold et al., 2016) to reduce also long-term readmissions.

In addition, the subgroup analyses showed that the continuity dimensions addressed by the interventions did interact with measure effectiveness. In particular, this effect is clearer when the interventions addressed all three continuity dimensions (informational, management and relational). Our findings confirm previous evidence in which the number of dimensions of continuity interventions were significantly related to their effectiveness (Bradley et al., 2013; Burke et al., 2014, Kripalani et al., 2014), and confirm the necessity to plan multimodal interventions that include as many continuity of care dimensions as possible (van Walraven et al., 2010v). It should be noted that management continuity is present in almost all of the RCTs analysed. This confirms the study by van Servellen et al. (2006), where management continuity is viewed as an integral part of any form of continuity without which neither informational nor relational continuity would be possible.

Finally, our review identified that the most used interventions were telephone follow-up and home visits in the short and long term group respectively. Literature confirms that telephone follow-up is the most frequently used 30-day post-discharge intervention, but also highlights inconclusive evidence about its effect (Mistiaen and Poot, 2006). As regards home visiting in the long term, it demonstrated a small relative effect that may not be clinically important (Mayo-Wilson et al., 2014).

Our review provides much needed evidence that continuity of care reduces short term hospital readmission, and may thus provide added value in the care of older people with chronic conditions. Clear recommendations have emerged from this review for primary care to improve continuity of care. Our research supports the importance of the *synchronization* of the three continuity dimensions during healthcare delivery. In fact, despite previous constant efforts to find the most effective interventions to reduce readmission, the key challenge is to provide different interventions addressing all of the continuity dimensions synchronously. Undoubtedly, any effective intervention will need to be implemented using a robust infrastructure of community services to provide ongoing assistance over time.

Moreover, the inconsistent effectiveness of continuity interventions in reducing long term readmission suggests that healthcare systems should be designed to support long term care of chronicity. With this aim it would also be necessary to plan wider and longer term interventions with reinforcement contacts able to modify patient behaviours (Cakir et al., 2017; Gupta and Fonarow, 2018). Besides, health policies should monitor long term readmissions by introducing strategies that force hospitals to pay attention to this outcome also, similar to the penalties for 30 day readmissions.

Finally, policymakers should recognize the need to reduce undesirable readmissions due to discontinuity of care and to promote continuity while improving the quality of care, thus increasing the value of the healthcare system by reducing cost without worsening quality.

Our study has several limitations. First, although we implemented comprehensive search strategies, we may not have identified all RCTs. Second, to enhance study homogeneity, we considered only studies measuring readmission rates as number of patients readmitted and with congruence between intervention and follow-up time.

The studies included comprised some multicomponent interventions differing substantially in their approach, thus it was nearly impossible to analyse which components of these made a difference to any of the outcomes assessed. Moreover, when labelling the types of continuity, some dimensions could not be clearly described or were difficult to extract, leading to an underestimation of the continuity accounted for. Finally, this review focused only on the hospital readmission outcome, and did not address other relevant health- or cost-related outcomes. Further research is needed to address the latter issues.

5. Conclusions

Continuity of care interventions prevent hospital readmissions in the short term in older people with chronic diseases. The evidence about the effectiveness of continuity interventions aiming to reduce long term readmissions, is inconclusive, suggesting the need to focus on it more strongly.

In particular, since long term readmissions are related to both clinical and socioeconomic factors, they could be prevented by closer cooperation and integration across different contextual boundaries (social, clinical, cultural), formal partnerships between acute-care hospitals and community-based organizations (Linertova et al., 2011).

Larger, well-conducted studies should continue to collect data on the effectiveness of continuity of care interventions in the long term.

Declaration of Competing Interest

The authors have no conflicts in the cover letter as well as in the manuscript, as noted above.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ijnurstu.2019.103396.

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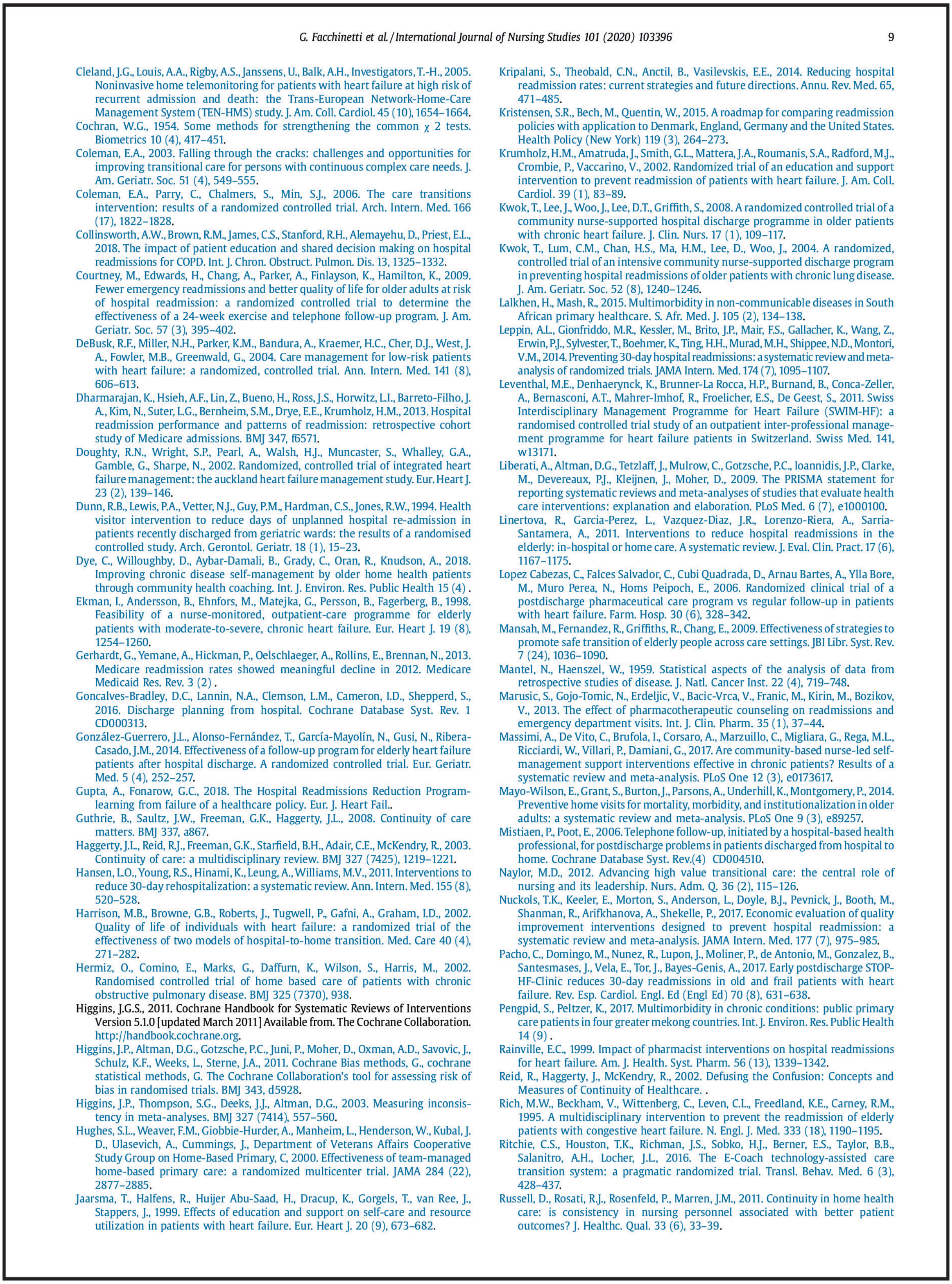

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Effectiveness of a primary care nurse delivered educational intervention for patients with type 2 diabetes mellitus in promoting metabolic control and compliance with long-term therapeutic targets: Randomised controlled trial

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ABSTRACT

Background: Systematic reviews and meta-analyses have shown very different values for the effectiveness of education in type 2 diabetes mellitus. However, the achievement of therapeutic targets after educational programs has been poorly evaluated.
Objective: Evaluate the effectiveness of a structured and individualised education program for type 2 diabetes, provided by a primary care nurse, which featured educational reinforcements and family support to achieve metabolic control, and long-term therapeutic targets.
Methods: Randomised controlled clinical trial with two arms: Intervention and control group. The intervention consisted of six face-to-face sessions of 30 min and follow-ups after 12 and 24 months for 236 participants with type 2 diabetes mellitus in a primary care setting in Andalusia (Spain). The primary outcome variables were the values and achievement of the type 2 diabetes mellitus control targets established by the American Diabetes Association: Glycated haemoglobin, fasting blood glucose, total cholesterol, low-density lipoprotein-cholesterol, high-density lipoprotein-cholesterol, triglycerides, systolic and diastolic blood pressure. The secondary outcome variable was body mass index.
Results: From an overall total of 236 participants, 54.2% were male and the average age was 65.1 ± 9.5. After 12 months, the glycated haemoglobin level and systolic blood pressure decreased in the intervention group. After 24 months, the following variables significantly improved among the intervention group participants: basal glycemia, glycated haemoglobin, total cholesterol low-density lipoprotein cholesterol, and diastolic blood pressure. The glycated haemoglobin target ($<7\%$) was better achieved in the intervention group than in the control group (35.2% vs 24.7%, $p < 0.003$). The rest of the targets were not met.
Conclusion: Continual diabetes education with reinforcement sessions provided by a nurse achieved reductions in glycated haemoglobin, basal glycaemia, total cholesterol, low-density lipoprotein-cholesterol and systolic blood pressure in both the medium and long term. It also increased the proportion of participants who achieved the therapeutic target of glycated haemoglobin.

What is already known about the topic?

- Evidence-based guidelines have established quality standards for diabetes education programs.
- The effectiveness of diabetes education in terms of improvements in glycated haemoglobin and other cardiovascular risk factors has shown very different values.

What this paper adds

- The structured and individualised, education intervention, delivered by an expert nurse, has been effective in reducing biochemical parameters in the medium and long term.

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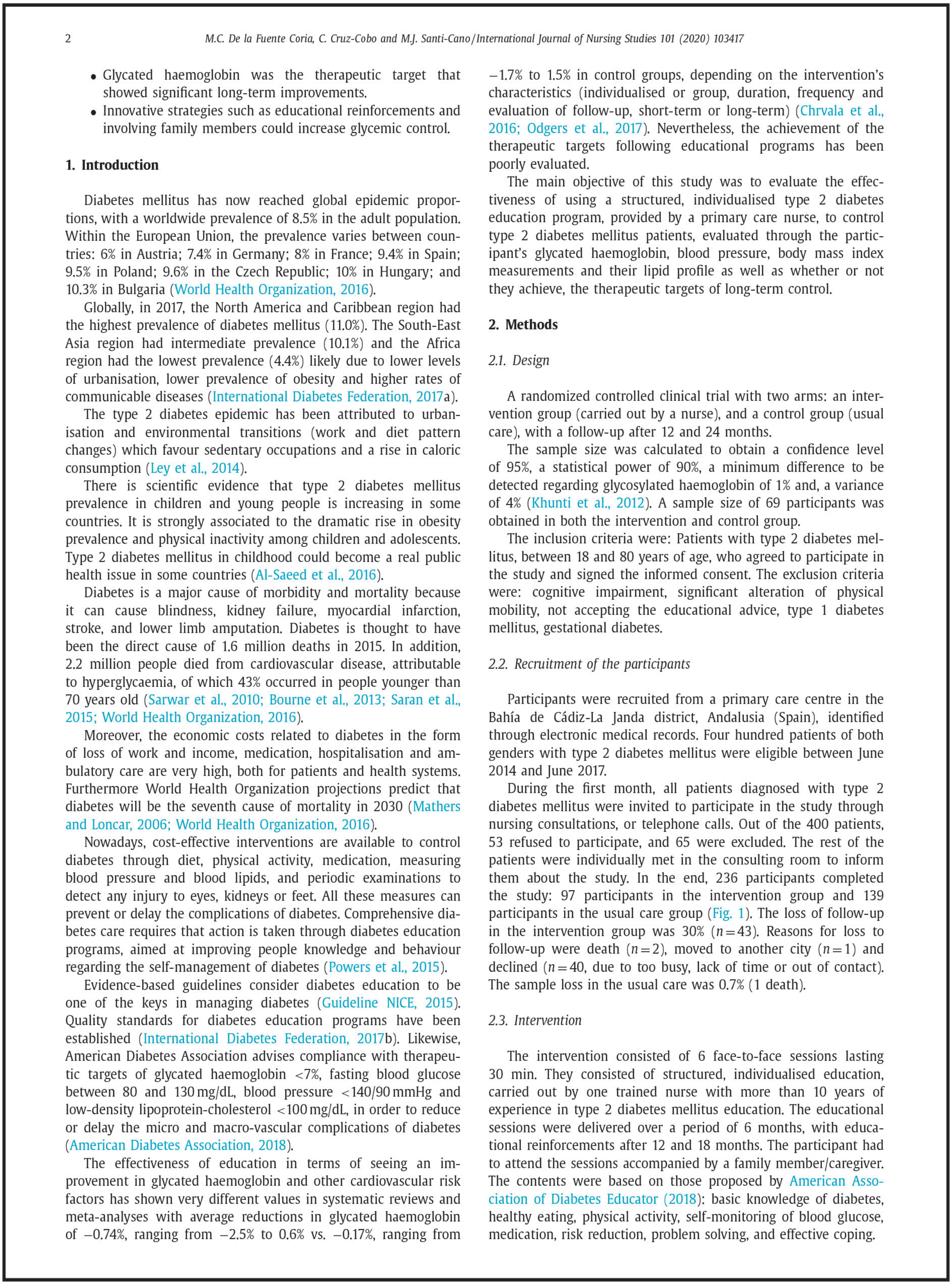

- Glycated haemoglobin was the therapeutic target that showed significant long-term improvements.
- Innovative strategies such as educational reinforcements and involving family members could increase glycemic control.

1. Introduction

Diabetes mellitus has now reached global epidemic proportions, with a worldwide prevalence of 8.5% in the adult population. Within the European Union, the prevalence varies between countries: 6% in Austria; 7.4% in Germany; 8% in France; 9.4% in Spain; 9.5% in Poland; 9.6% in the Czech Republic; 10% in Hungary; and 10.3% in Bulgaria (World Health Organization, 2016).

Globally, in 2017, the North America and Caribbean region had the highest prevalence of diabetes mellitus (11.0%). The South-East Asia region had intermediate prevalence (10.1%) and the Africa region had the lowest prevalence (4.4%) likely due to lower levels of urbanisation, lower prevalence of obesity and higher rates of communicable diseases (International Diabetes Federation, 2017a).

The type 2 diabetes epidemic has been attributed to urbanisation and environmental transitions (work and diet pattern changes) which favour sedentary occupations and a rise in caloric consumption (Ley et al., 2014).

There is scientific evidence that type 2 diabetes mellitus prevalence in children and young people is increasing in some countries. It is strongly associated to the dramatic rise in obesity prevalence and physical inactivity among children and adolescents. Type 2 diabetes mellitus in childhood could become a real public health issue in some countries (Al-Saeed et al., 2016).

Diabetes is a major cause of morbidity and mortality because it can cause blindness, kidney failure, myocardial infarction, stroke, and lower limb amputation. Diabetes is thought to have been the direct cause of 1.6 million deaths in 2015. In addition, 2.2 million people died from cardiovascular disease, attributable to hyperglycaemia, of which 43% occurred in people younger than 70 years old (Sarwar et al., 2010; Bourne et al., 2013; Saran et al., 2015; World Health Organization, 2016).

Moreover, the economic costs related to diabetes in the form of loss of work and income, medication, hospitalisation and ambulatory care are very high, both for patients and health systems. Furthermore World Health Organization projections predict that diabetes will be the seventh cause of mortality in 2030 (Mathers and Loncar, 2006; World Health Organization, 2016).

Nowadays, cost-effective interventions are available to control diabetes through diet, physical activity, medication, measuring blood pressure and blood lipids, and periodic examinations to detect any injury to eyes, kidneys or feet. All these measures can prevent or delay the complications of diabetes. Comprehensive diabetes care requires that action is taken through diabetes education programs, aimed at improving people knowledge and behaviour regarding the self-management of diabetes (Powers et al., 2015).

Evidence-based guidelines consider diabetes education to be one of the keys in managing diabetes (Guideline NICE, 2015). Quality standards for diabetes education programs have been established (International Diabetes Federation, 2017b). Likewise, American Diabetes Association advises compliance with therapeutic targets of glycated haemoglobin <7%, fasting blood glucose between 80 and 130 mg/dL, blood pressure <140/90 mmHg and low-density lipoprotein-cholesterol <100 mg/dL, in order to reduce or delay the micro and macro-vascular complications of diabetes (American Diabetes Association, 2018).

The effectiveness of education in terms of seeing an improvement in glycated haemoglobin and other cardiovascular risk factors has shown very different values in systematic reviews and meta-analyses with average reductions in glycated haemoglobin of −0.74%, ranging from −2.5% to 0.6% vs. −0.17%, ranging from −1.7% to 1.5% in control groups, depending on the intervention's characteristics (individualised or group, duration, frequency and evaluation of follow-up, short-term or long-term) (Chrvala et al., 2016; Odgers et al., 2017). Nevertheless, the achievement of the therapeutic targets following educational programs has been poorly evaluated.

The main objective of this study was to evaluate the effectiveness of using a structured, individualised type 2 diabetes education program, provided by a primary care nurse, to control type 2 diabetes mellitus patients, evaluated through the participant's glycated haemoglobin, blood pressure, body mass index measurements and their lipid profile as well as whether or not they achieve, the therapeutic targets of long-term control.

2. Methods

2.1. Design

A randomized controlled clinical trial with two arms: an intervention group (carried out by a nurse), and a control group (usual care), with a follow-up after 12 and 24 months.

The sample size was calculated to obtain a confidence level of 95%, a statistical power of 90%, a minimum difference to be detected regarding glycosylated haemoglobin of 1% and, a variance of 4% (Khunti et al., 2012). A sample size of 69 participants was obtained in both the intervention and control group.

The inclusion criteria were: Patients with type 2 diabetes mellitus, between 18 and 80 years of age, who agreed to participate in the study and signed the informed consent. The exclusion criteria were: cognitive impairment, significant alteration of physical mobility, not accepting the educational advice, type 1 diabetes mellitus, gestational diabetes.

2.2. Recruitment of the participants

Participants were recruited from a primary care centre in the Bahía de Cádiz-La Janda district, Andalusia (Spain), identified through electronic medical records. Four hundred patients of both genders with type 2 diabetes mellitus were eligible between June 2014 and June 2017.

During the first month, all patients diagnosed with type 2 diabetes mellitus were invited to participate in the study through nursing consultations, or telephone calls. Out of the 400 patients, 53 refused to participate, and 65 were excluded. The rest of the patients were individually met in the consulting room to inform them about the study. In the end, 236 participants completed the study: 97 participants in the intervention group and 139 participants in the usual care group (Fig. 1). The loss of follow-up in the intervention group was 30% ($n = 43$). Reasons for loss to follow-up were death ($n = 2$), moved to another city ($n = 1$) and declined ($n = 40$, due to too busy, lack of time or out of contact). The sample loss in the usual care was 0.7% (1 death).

2.3. Intervention

The intervention consisted of 6 face-to-face sessions lasting 30 min. They consisted of structured, individualised education, carried out by one trained nurse with more than 10 years of experience in type 2 diabetes mellitus education. The educational sessions were delivered over a period of 6 months, with educational reinforcements after 12 and 18 months. The participant had to attend the sessions accompanied by a family member/caregiver. The contents were based on those proposed by American Association of Diabetes Educator (2018): basic knowledge of diabetes, healthy eating, physical activity, self-monitoring of blood glucose, medication, risk reduction, problem solving, and effective coping.

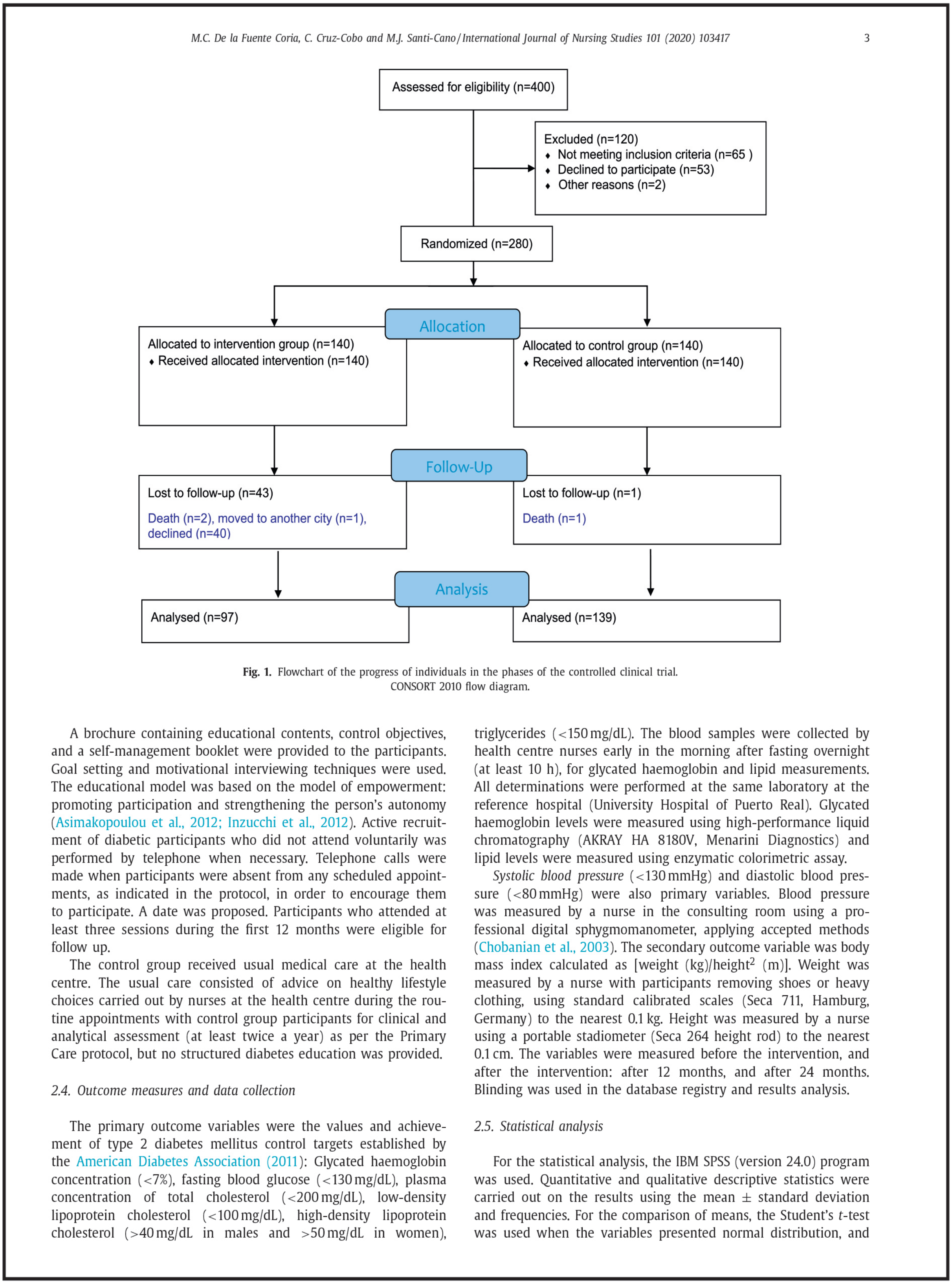

Fig. 1. Flowchart of the progress of individuals in the phases of the controlled clinical trial. CONSORT 2010 flow diagram.

A brochure containing educational contents, control objectives, and a self-management booklet were provided to the participants. Goal setting and motivational interviewing techniques were used. The educational model was based on the model of empowerment: promoting participation and strengthening the person's autonomy (Asimakopoulou et al., 2012; Inzucchi et al., 2012). Active recruitment of diabetic participants who did not attend voluntarily was performed by telephone when necessary. Telephone calls were made when participants were absent from any scheduled appointments, as indicated in the protocol, in order to encourage them to participate. A date was proposed. Participants who attended at least three sessions during the first 12 months were eligible for follow up.

The control group received usual medical care at the health centre. The usual care consisted of advice on healthy lifestyle choices carried out by nurses at the health centre during the routine appointments with control group participants for clinical and analytical assessment (at least twice a year) as per the Primary Care protocol, but no structured diabetes education was provided.

2.4. Outcome measures and data collection

The primary outcome variables were the values and achievement of type 2 diabetes mellitus control targets established by the American Diabetes Association (2011): Glycated haemoglobin concentration (<7%), fasting blood glucose (<130 mg/dL), plasma concentration of total cholesterol (<200 mg/dL), low-density lipoprotein cholesterol (<100 mg/dL), high-density lipoprotein cholesterol (>40 mg/dL in males and >50 mg/dL in women), triglycerides (<150 mg/dL). The blood samples were collected by health centre nurses early in the morning after fasting overnight (at least 10 h), for glycated haemoglobin and lipid measurements. All determinations were performed at the same laboratory at the reference hospital (University Hospital of Puerto Real). Glycated haemoglobin levels were measured using high-performance liquid chromatography (AKRAY HA 8180V, Menarini Diagnostics) and lipid levels were measured using enzymatic colorimetric assay.

Systolic blood pressure (<130 mmHg) and diastolic blood pressure (<80 mmHg) were also primary variables. Blood pressure was measured by a nurse in the consulting room using a professional digital sphygmomanometer, applying accepted methods (Chobanian et al., 2003). The secondary outcome variable was body mass index calculated as [weight (kg)/height^2 (m)]. Weight was measured by a nurse with participants removing shoes or heavy clothing, using standard calibrated scales (Seca 711, Hamburg, Germany) to the nearest 0.1 kg. Height was measured by a nurse using a portable stadiometer (Seca 264 height rod) to the nearest 0.1 cm. The variables were measured before the intervention, and after the intervention: after 12 months, and after 24 months. Blinding was used in the database registry and results analysis.

2.5. Statistical analysis

For the statistical analysis, the IBM SPSS (version 24.0) program was used. Quantitative and qualitative descriptive statistics were carried out on the results using the mean ± standard deviation and frequencies. For the comparison of means, the Student's *t*-test was used when the variables presented normal distribution, and

Table 1
Baseline data for intervention and control groups.

Variables	TG $n = 236$	IG $n = 97$	CG $n = 139$	P
Age (years)	65.1 ± 9.5	64.5 ± 9.6	65.5 ± 9.5	0.434
Males %(n)	54.2 (128)	54.6 (53)	54.0 (75)	1.000
Diabetes years	7.6 + 4.1	8.8 ± 4.4	6,7 ± 3,6	0.000[a]
BMI (kg/m^2)	30.8 ± 4.3	31.4 ± 4.5	29.3 ± 3.6	0.022
SBP (mmHg)	135.91 ± 17.28	133.47 ± 16.79	138.22 ± 17.50	0.112
DBP (mmHg)	77.19 ± 10.20	76.79 ± 9.10	77.57 ± 11.14	0.941
FBG (mg/dl)	145.0 ± 45.0	140.5 ± 35.3	148.2 ± 50.6	0.255
HbA1c 1 (%)	7.5 ± 1.4	7.6 ± 1.4	7.4 ± 1.5	0.532
TC (mg/dl)	204.2 ± 40.0	199.0 ± 38.8	208.9 ± 40.7	0.109
LDL-c (mg/dl)	121.3 ± 34.3	115.4 ± 32.9	125.9 ± 34.8	0.077
HDL-c (mg/dl)	49.3 ± 13.1	48.0 ± 12.9	50.3 ± 13.2	0.270
TG (mg/dl)	159.6 ± 84.8	146.2 ± 62.4	169.0 ± 96.5	0.075
Diet/exercise treatment	6.8 (15)	7.3 (7)	6.5 (8)	0.795
OADs treatment	67.7 (149)	67.7 (65)	67.6 (84)	1.000
Insulin treatment %	25.5 (56)	25.0 (24)	25.8 (32)	1.000

TG: Total Group. IG: Intervention Group. CG: Control Group.

[a] Mann–Whitney U test. BMI 1: body mass index at the beginning of the study. SBP 1: systolic blood pressure at the beginning of the study. DBP 1: diastolic blood pressure at the beginning of the study. FBG: fasting blood glucose. HbA1c 1: glycated haemoglobin at the beginning of the study. TC 1: total cholesterol at the beginning of the study. LDL-c: cholesterol bound to low density lipoprotein at the beginning of the study. HDL-c: cholesterol bound to high density lipoprotein at the beginning of the study. TG: triglycerides. OADs: oral antidiabetics.

the Mann–Whitney U and Wilcoxon tests were applied if the variables were not normally distributed. For the comparison of proportions, the Pearson Chi-square test was used. A value of $p < 0.05$ was considered statistically significant.

2.6. Ethical considerations

The study was conducted under the standards and ethical criteria of the Helsinki declaration, and was submitted to the approval of the Ethics and Research Committee of the Bahía de Cádiz-La Janda Health District. All participants were informed about the nature of the study and their consent to participate in it was requested.

3. Results

The baseline characteristics of the participants are shown in Table 1. Among these participants, 54.2% were male, and the mean age was similar in both groups 65.1 ± 9.5. The mean number of years of onset of type 2 diabetes mellitus was 7.6 years ± 4.1 years, somewhat lower in the control group. At the beginning of the study, both groups were comparable since no statistically significant differences were observed in the outcome variables between the intervention and control groups, except for lower body mass index in the control group. The baseline glycated haemoglobin levels in the intervention and control groups were moderately elevated and similar in both groups. (7.6% vs 7.4, $p = 0.532$).

Table 2 shows the mean values ± standard deviation and the difference of means, 95% CI, of the outcome variables after 12 and 24 months of follow-up. After 12 months of follow-up, a decrease in glycated haemoglobin was observed in the intervention group, but not in the control group (−0.55, 95% CI −0.20, −0.90, $p < 0.001$ vs +0.06, −0.14, +0.28, $p = 0.530$). However, the difference between the groups was not statistically significant at this stage of follow-up. Systolic blood pressure was statistically lower after 12 months in the intervention group (−1.7, 95% CI −5.2, +1.8 vs +0.9, 95% CI −3.6, +5.5, $p < 0.024$).

After 24 months of follow-up, a significant decrease in fasting blood glucose was detected in the intervention group (−8.1 mg/dL, 95% CI −19.8, +3.4 $p < 0.015$). Decreases were also detected in glycated haemoglobin (−0.82%, 95% CI −0.50, −1.14, vs +0.08, 95% CI −0.20, +0.37, $p = 0.003$), total cholesterol (−17.7 mg/dL, 95% CI −26.7, −8.7 vs −2.3, 95% CI −12.5, + 7.8, $p < 0.008$), low-density lipoprotein cholesterol (−12.1 mg/dL, 95% CI −21.0, −3.1 vs −1.2, 95% CI −11.8, +9.3, $p < 0.040$), and systolic blood pressure (−3.5 mmHg, 95% CI% −7.7, + 0.5 vs +2.6, 95% CI −1.3, +6.7, $p < 0.000$). High-density lipoprotein cholesterol, triglycerides, diastolic blood pressure and body mass index values were not modified.

With regard to the achievement of therapeutic objectives (Table 3), attaining the glycated haemoglobin target (<7%) was statistically higher after 24 months in the intervention group: 35.2% vs 24.7%, $p < 0.003$. There was no improvement of the control goal in other variables: fasting blood glucose, total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglycerides, or blood pressure.

4. Discussion

Our study found that the educational intervention had favourable effects in the medium and long term on fasting blood glucose, glycated haemoglobin, total cholesterol, low-density lipoprotein cholesterol and systolic blood pressure. Likewise, the therapeutic objective that showed significant long-term improvements with the educational intervention was glycated haemoglobin.

At the beginning of the study, both intervention and control groups were comparable as shown by the similar figures in the outcome variables (Table 1). Baseline glycated haemoglobin levels were not excessively high (7.6% vs 7.4, $p = 0.532$). In general, studies that include participants with higher baseline glycated haemoglobin levels (8–9%) tend to experience more significant differences than those with lower levels (Chrvala et al., 2016).

Response rates of our study were high after two years of follow-up: 70% of participants in the intervention group and 99% in the control group. This compares positively with other self-management education interventions that obtained long term follow up data in the intervention group from 51% (Mohamed et al., 2013) to 60% (Eakin et al., 2014) of the original participants. Overall, interventions and follow up periods of shorter duration have shown lower loss of follow up (Kim et al., 2015; Merakou et al., 2015). However, some of these programmes have found no difference in biomedical outcomes at long term (Khunti et al., 2012; Mash et al., 2014). The optimal dose of intervention would have to be examined in further studies. The attendance of participants at educational sessions and therefore exposure to the intervention is also considered as an important factor in the success of the educational programme.

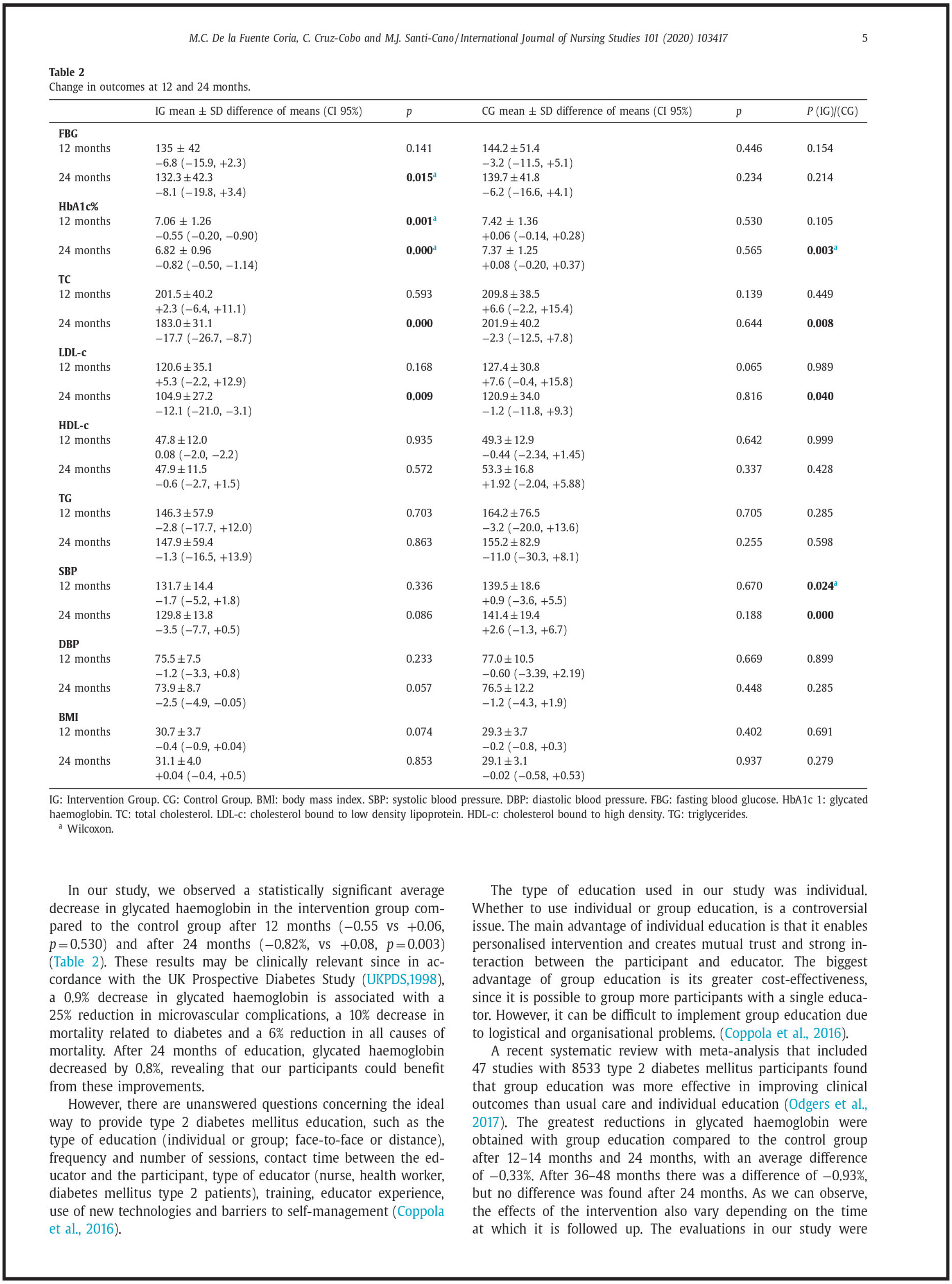

Table 2
Change in outcomes at 12 and 24 months.

	IG mean ± SD difference of means (CI 95%)	*p*	CG mean ± SD difference of means (CI 95%)	*p*	*P* (IG)/(CG)
FBG					
12 months	135 ± 42 −6.8 (−15.9, +2.3)	0.141	144.2 ± 51.4 −3.2 (−11.5, +5.1)	0.446	0.154
24 months	132.3 ± 42.3 −8.1 (−19.8, +3.4)	**0.015**[a]	139.7 ± 41.8 −6.2 (−16.6, +4.1)	0.234	0.214
HbA1c%					
12 months	7.06 ± 1.26 −0.55 (−0.20, −0.90)	**0.001**[a]	7.42 ± 1.36 +0.06 (−0.14, +0.28)	0.530	0.105
24 months	6.82 ± 0.96 −0.82 (−0.50, −1.14)	**0.000**[a]	7.37 ± 1.25 +0.08 (−0.20, +0.37)	0.565	**0.003**[a]
TC					
12 months	201.5 ± 40.2 +2.3 (−6.4, +11.1)	0.593	209.8 ± 38.5 +6.6 (−2.2, +15.4)	0.139	0.449
24 months	183.0 ± 31.1 −17.7 (−26.7, −8.7)	**0.000**	201.9 ± 40.2 −2.3 (−12.5, +7.8)	0.644	**0.008**
LDL-c					
12 months	120.6 ± 35.1 +5.3 (−2.2, +12.9)	0.168	127.4 ± 30.8 +7.6 (−0.4, +15.8)	0.065	0.989
24 months	104.9 ± 27.2 −12.1 (−21.0, −3.1)	**0.009**	120.9 ± 34.0 −1.2 (−11.8, +9.3)	0.816	**0.040**
HDL-c					
12 months	47.8 ± 12.0 0.08 (−2.0, −2.2)	0.935	49.3 ± 12.9 −0.44 (−2.34, +1.45)	0.642	0.999
24 months	47.9 ± 11.5 −0.6 (−2.7, +1.5)	0.572	53.3 ± 16.8 +1.92 (−2.04, +5.88)	0.337	0.428
TG					
12 months	146.3 ± 57.9 −2.8 (−17.7, +12.0)	0.703	164.2 ± 76.5 −3.2 (−20.0, +13.6)	0.705	0.285
24 months	147.9 ± 59.4 −1.3 (−16.5, +13.9)	0.863	155.2 ± 82.9 −11.0 (−30.3, +8.1)	0.255	0.598
SBP					
12 months	131.7 ± 14.4 −1.7 (−5.2, +1.8)	0.336	139.5 ± 18.6 +0.9 (−3.6, +5.5)	0.670	**0.024**[a]
24 months	129.8 ± 13.8 −3.5 (−7.7, +0.5)	0.086	141.4 ± 19.4 +2.6 (−1.3, +6.7)	0.188	**0.000**
DBP					
12 months	75.5 ± 7.5 −1.2 (−3.3, +0.8)	0.233	77.0 ± 10.5 −0.60 (−3.39, +2.19)	0.669	0.899
24 months	73.9 ± 8.7 −2.5 (−4.9, −0.05)	0.057	76.5 ± 12.2 −1.2 (−4.3, +1.9)	0.448	0.285
BMI					
12 months	30.7 ± 3.7 −0.4 (−0.9, +0.04)	0.074	29.3 ± 3.7 −0.2 (−0.8, +0.3)	0.402	0.691
24 months	31.1 ± 4.0 +0.04 (−0.4, +0.5)	0.853	29.1 ± 3.1 −0.02 (−0.58, +0.53)	0.937	0.279

IG: Intervention Group. CG: Control Group. BMI: body mass index. SBP: systolic blood pressure. DBP: diastolic blood pressure. FBG: fasting blood glucose. HbA1c 1: glycated haemoglobin. TC: total cholesterol. LDL-c: cholesterol bound to low density lipoprotein. HDL-c: cholesterol bound to high density. TG: triglycerides.

[a] Wilcoxon.

In our study, we observed a statistically significant average decrease in glycated haemoglobin in the intervention group compared to the control group after 12 months (−0.55 vs +0.06, $p = 0.530$) and after 24 months (−0.82%, vs +0.08, $p = 0.003$) (Table 2). These results may be clinically relevant since in accordance with the UK Prospective Diabetes Study (UKPDS,1998), a 0.9% decrease in glycated haemoglobin is associated with a 25% reduction in microvascular complications, a 10% decrease in mortality related to diabetes and a 6% reduction in all causes of mortality. After 24 months of education, glycated haemoglobin decreased by 0.8%, revealing that our participants could benefit from these improvements.

However, there are unanswered questions concerning the ideal way to provide type 2 diabetes mellitus education, such as the type of education (individual or group; face-to-face or distance), frequency and number of sessions, contact time between the educator and the participant, type of educator (nurse, health worker, diabetes mellitus type 2 patients), training, educator experience, use of new technologies and barriers to self-management (Coppola et al., 2016).

The type of education used in our study was individual. Whether to use individual or group education, is a controversial issue. The main advantage of individual education is that it enables personalised intervention and creates mutual trust and strong interaction between the participant and educator. The biggest advantage of group education is its greater cost-effectiveness, since it is possible to group more participants with a single educator. However, it can be difficult to implement group education due to logistical and organisational problems. (Coppola et al., 2016).

A recent systematic review with meta-analysis that included 47 studies with 8533 type 2 diabetes mellitus participants found that group education was more effective in improving clinical outcomes than usual care and individual education (Odgers et al., 2017). The greatest reductions in glycated haemoglobin were obtained with group education compared to the control group after 12–14 months and 24 months, with an average difference of −0.33%. After 36–48 months there was a difference of −0.93%, but no difference was found after 24 months. As we can observe, the effects of the intervention also vary depending on the time at which it is followed up. The evaluations in our study were

Table 3
Compliance with targets at 12 and 24 months.

Variables % (n)	Total $n = 236$	IG $n = 97$	p within the IG[a]	CG $n = 139$	p within the CG[a]	p IG/CG
FBG baseline	41.6 (77)	38.2 (29)		44.0 (48)		0.452
12 months	48.3 (98)	53.4 (47)	**0.031**	44.3 (51)	1.000	0.206
24 meses	51.5 (103)	25,5 (51)	**0.008**	26.0 (52)	0.424	0.203
HbA1c baseline	44.6 (75)	40.7 (33)		48.3 (42)		0.354
12 months	53.3 (104)	59.1 (55)	**0.011**	48.0 (49)	0.481	0.151
24 months	59.9 (109)	35.2 (64)	**0.001**	24.7 (45)	0.383	**0.003**
TC baseline	50.9 (85)	55.7 (44)		46.6 (41)		0.279
12 months	44.0 (81)	45.7 (42)	0.263	42.4 (39)	0.238	0.767
24 months	55.8 (106)	28.4 (54)	0.078	27.4 (52)	1.000	0.142
LDL-c baseline	27.4 (37)	32.2 (19)		23.7 (18)		0.332
12 months	22.3 (39)	23.9 (21)	0.503	20.7 (18)	0.109	0.717
24 months	30.9 (54)	14.9 (26)	0.267	16.0 (28)	0.267	0.746
HDL-c baseline	63.2 (98)	64.8 (46)		61.9 (52)		0.741
12 months	60.6 (106)	59.1 (52)	0.227	62.1 (54)	1.000	0.758
24 months	65.0 (115)	31.1 (55)	0.553	33.9 (60)	1.000	0.755
TG baseline	56.7 (102)	60.8 (45)		53.8 (57)		0.364
12 months	56.9 (99)	61.2 (52)	1.000	52.8 (47)	0.571	0.287
24 months	62.8 (120)	30.4 (58)	0.134	32.5 (62)	0.265	0.552
BP baseline	17.2 (30)	17.6 (15)		16.9 (15)		0.615
12 months	20.0 (39)	23.4 (22)	0.344	16.8 (17)	0.617	0.285
24 months	23.3 (44)	11.6 (22)	0.307	11.6 (22)	0.371	0.604

IG: Intervention Group. CG: Control Group. BMI: body mass index. BP: blood pressure. FBG: fasting blood glucose. HbA1c 1: glycated haemoglobin. TC: total cholesterol. LDL-c: cholesterol bound to low density lipoprotein. HDL-c: cholesterol bound to high density. TG: triglycerides.

[a] McNemar. Target of BG $\leq$ 130 mg/dl%, Target of HbA1c $<$ 7%, Target of TC $\leq$ 200 mg/dL, target of LDL-c $<$ 100 mg/dL, target of HDL-c males $>$ 40 mg/dL women $>$ 50 mg/dL, target of TG $<$ 150 mg/dl, target of BP $<$ 130/80 mmHg.

performed for medium term (after 12 months) and long term (after 24 months) outcomes. In both, beneficial effects were observed in the variables studied.

Chrvala et al. (2016) performed a systematic review of 118 studies, in which they observed an average reduction in glycated haemoglobin of 0.74% in the intervention group and 0.17% in the control group. They state that the programs that used a combination of individual and group methods obtained the best results in decreasing of glycated haemoglobin (−1.10%) compared with only group (−0.62%) or individual education (−0.78%).

The number and frequency of education sessions, as well as the ideal total contact time between the educator and the patient are also controversial issues. In the aforementioned meta-analysis by Odgers et al. (2017), the greatest reduction in glycated haemoglobin was obtained in longer intervention periods (13–60 months) (−0.66%), compared to shorter interventions (<1 month, 1–3 months, 4–6 months, 7–12 months); <5 sessions (−0.46%) compared to more numerous ones (6–10 sessions, 11–20 sessions and > 21 sessions); ≤ 8 h contact time (−0.45%) compared to those with a higher number of hours (9–12 h, 13–18 h, 19–30 h, ≥31 h); and with the participation of a family member (−0.36%). The intervention in our study consisted of six educational sessions of 20–30 min over 18 months. Four of the sessions took place in the first 6 months with reinforcements after 12 and 18 months. The total contact time was 2–3 h. The participant agreed that they would attend the diabetes education sessions with a family member. Family involvement and support is important to achieve the objectives that are proposed.

In contrast, in the aforementioned systematic review by Chrvala et al. (2016), several studies that obtained a significant reduction in glycated haemoglobin emphasized a higher number of contact hours. Furthermore, in patients with high glycated haemoglobin values (>9%), a significant decrease was also observed. The authors concluded that the way education is provided, its contact hours and the baseline glycated haemoglobin influence improvements in glycated haemoglobin.

Another study conducted in the USA, examined a mixed intervention (group and later individual telephone advice once a month) over 12 months. It achieved a reduction of 1–1.3% glycated haemoglobin (Kim et al., 2015). On the contrary, in a study carried out in Australia, in which the intervention consisted only of telephone calls over a period of 18 months, evaluated after 24 months, no changes were obtained in metabolic markers (Eakin et al., 2014).

In our study, as well as the initial 6 months of diabetes education, we performed reinforcement sessions after 12 and 18 months. There is evidence that educators who contact their diabetes mellitus patients more regularly have better results (Chrvala et al., 2016). The importance of continuing education is evident in short studies (4 months) that do not observe metabolic changes one year after the intervention (Mash et al., 2014). The results obtained from the educational intervention generally drop over time. Therefore, it is important to reinforce education through regular sessions. In a recent systematic review of the effectiveness of diabetes education in Chinese adults, the authors concluded that glycemic control was better in studies that used continuous education with information reinforcement strategies (Choi et al., 2016).

As for the type of educator, in our study, the diabetes education was provided by a primary care nurse. Different studies have shown the effectiveness of diabetes education DE provided by different types of educators and levels of training: nurses, doctors, dieticians or nutritionists, health teams, health workers or diabetes mellitus patients. However, nurses are the most common educators (Coppola et al., 2016).

Regarding the other outcome variables, fasting blood glucose in the meta-analysis of Odgers et al. (2017) 0.68 mmol/L (12 mg/dL) decreased, only after 12–14 months, but not at the other time intervals. The fasting blood glucose figure should be maintained <130 mg/dL in individuals with type 2 diabetes mellitus (American Diabetes Association, 2018) to reduce the progression of microvascular complications. In our study, fasting blood glucose decreased significantly by 8 mg/dL in the intervention group after 24 months, but not in the control group. However, the data suggest that the improvements in fasting blood glucose appear to be less clinically important than those of glycated haemoglobin.

With regard to body mass index, our results show no significant decreases after the intervention. It is known that sustained weight loss (>12 months) of 5 kg in patients with diabetes melli-

tus type 2 improves fasting blood glucose, lipid profile, and blood pressure. These results coincide with previous systematic reviews. In the study by Odgers et al. (2017) body mass index was not significantly modified either.

Our results show significant improvements after the 24 months interventions, both in total cholesterol and low-density-lipoprotein cholesterol and after 12 and 24 months in the systolic blood pressure. The clinical significance of these results is highlighted, since improving lipids and controlling of blood pressure in diabetes mellitus type 2 patients can reduce the risk of micro and macrovascular complications (Stratton et al., 2000). Nevertheless, Odgers et al. (2017) did not observe significant changes in systolic blood pressure, total cholesterol, low-density lipoprotein cholesterol, or high-density lipoprotein cholesterol.

A study conducted in Sweden, featuring education over 6 months and a 12 month follow-up, showed that both group and individual education were similar in terms of reducing glycated haemoglobin (−0.5% and −0.4%) after 12 months. However, the rest of the anthropometric and lipid variables were not modified (Jutterstrom et al., 2016). Unlike these studies, in Greece, a brief 3-week group intervention using conversational mapping saw improvements in glycated haemoglobin, lipids, and body mass index, after 6 months (Merakou et al., 2015).

Another group study (4 sessions: 4 h) developed in Qatar, found a decrease in glycated haemoglobin and body mass index after 12 months, but not in the lipid profile (Mohamed et al., 2013). A Belgian study, using telephone telecoaching, managed to reduce glycated haemoglobin, lipids and body mass index (Odnoletkova et al., 2016). Pérez et al. (2015) also observed with their diabetes education program that they had a positive impact on glycated haemoglobin, but not on lipids or body mass index. Similarly, in a study carried out by health workers in the US, with a 12-month, 7-h individual education program, glycated haemoglobin decreased, but not blood pressure BP, body mass index BMI, or lipids (Prezio et al., 2013). A recent meta-analysis that included 28 studies, showed that culturally adapted education resulted in a reduction in glycated haemoglobin over a 24-month period. However, it did not obtain benefits in other variables such as blood pressure and lipids (Creamer et al., 2016). Therefore, the variable that decrease most frequently is glycated haemoglobin. Body mass index, blood pressure and plasma lipids do not usually benefit from the intervention in the same way.

With regard to achieving therapeutic objectives, our study found that achieving glycated haemoglobin <7% target was significantly higher in the intervention group than in the control group (35.2% vs. 24.7%, $p = 0.003$), while the rest of the objectives (fasting blood glucose, lipids and blood pressure) were not improved. Due to scientific evidence showing that the control of these factors helps to reduce type 2 diabetes mellitus complications, the American Diabetes Association advises to achieve the therapeutic objectives for these patients (American Diabetes Association, 2018). However, there are studies that show that achieving of the three therapeutic targets (glycated haemoglobin <7%, low-density lipoprotein-cholesterol <100 mg/dL and blood pressure <130–80 mmHg) happens in only 18.8% of American diabetic patients (Stark et al., 2013). In addition, in most diabetes education trials, the reduction in the figures of each variable after the intervention is analysed, but target achievements is not.

There are many barriers to self-managing diabetes mellitus type 2 including cultural, motivational and, cognitive as well as poor self-management skills. These must be identified by educators. For this purpose, individual sessions may be more useful than group sessions. Individual sessions can also be episodically used even when the education program is based on group sessions (Coppola et al., 2016). A recent systematic review has shown that the cost of education programs for diabetes self-management is modest and probably cost-effective in the long term (Lian et al., 2017).

The strengths of the present trial include the recruitment of a representative sample of patients with diabetes mellitus type 2 in primary care, long-term follow-up (24 months), the goal of evaluating the achievement of therapeutic targets, and the homogeneity of baseline figures in the intervention and control group. All these signal that the intervention carried out produced a favourable response in the clinical parameters.

4.1. Limitations

Among the limitations of the trial, it should be noted that no blinding was used regarding group allocation, which is difficult in this type of study. Secondly, changes in medication were not taken into account. Medication adjustments in these participants are inevitable, and they may have an influence both on the intervention and control group. Finally, the sample came from a single health centre. Therefore, the results cannot be generalised for the entire population. However, as we can see, the figures of the outcome variables are similar to those observed in the different reviews and meta-analyses, which support the representativeness of the sample.

4.2. Implications for practice

The present study has clinical and research implications. Education in diabetes can optimise glycemic control in patients, and ongoing diabetes education intervention can achieve favourable long-term results. Thus, innovative strategies such as educational reinforcements and family involvement could increase glycemic control. The educator's level of qualification and continual training; the availability of material and human resources; and the planning and continuous evaluation of the diabetes education programs are necessary to strengthen this program.

5. Conclusion

In conclusion, this study shows that our educational intervention in diabetes provided by a primary care nurse over six months, with reinforcement sessions after 12 and 18 months, together with family support can achieve reductions in glycated haemoglobin, fasting blood glucose, total cholesterol, low-density lipoprotein cholesterol and systolic blood pressure in the medium and long term. It also causes an increase in the number of participants who meet the therapeutic target of glycated haemoglobin. Our intervention could be interpreted as a way of delaying the progression of the disease.

Conflict of interest

None.

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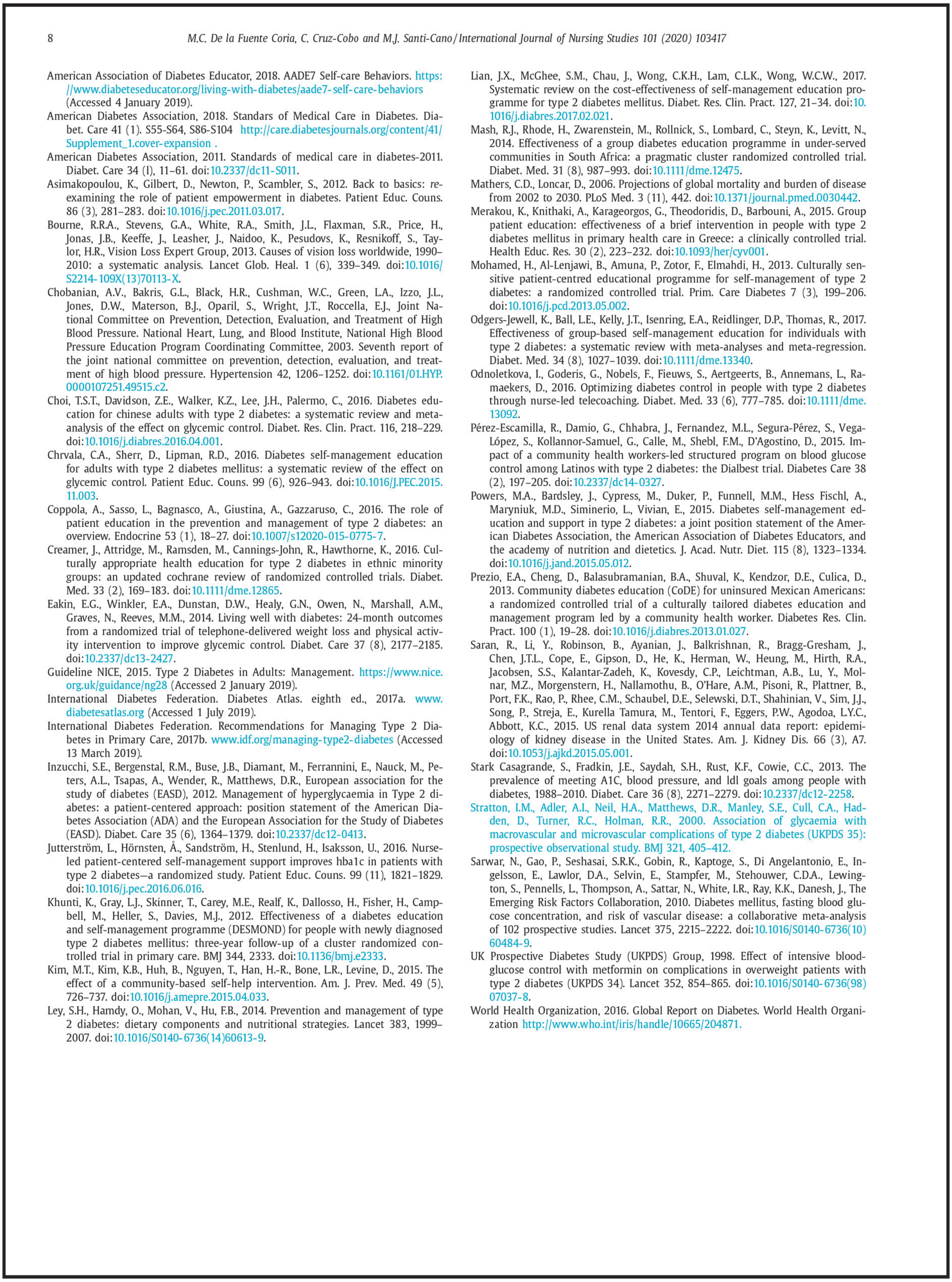

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Effectiveness of a Staff Resilience Program in a Pediatric Intensive Care Unit

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ABSTRACT

Background: Compassion fatigue (CF) and secondary traumatic stress (STS) is prevalent in intensive care nurses, especially in pediatric intensive care nurses (PICU). CF, which includes STS and burnout, leads to reduced employee engagement and nursing turnover.
Purpose: The purpose of this project was to evaluate the impact of a staff resilience program on nursing turnover, employee engagement and compassion satisfaction among nurses in a PICU.
Design and methods: A retrospective pre-test and post-test design was used to evaluate the impact of a staff resilience program on turnover, engagement, and Professional Quality of Life (ProQOL), which measured compassion satisfaction and compassion fatigue.
Results: RN turnover was reduced and employee engagement was improved, although the differences were not statistically significant. The aggregate scores of the ProQOL indicated the RN's had low levels of CF with high levels of compassion satisfaction post implementation of the resilience program. Years of work experience was positively associated with compassion satisfaction and work engagement.
Conclusions: Education regarding the prevention of CF and burnout coupled with interventions designed to promote resilience can be effective in reducing CF and in building compassion satisfaction.
Practice implications: Doing an assessment of compassion fatigue and following up with the implementation of interventions to build staff resilience and promote psychological health can lead to positive outcomes, as demonstrated by the increase in work engagement and compassion satisfaction when burnout and CF decreased.

Introduction

As the healthcare environment continues to change and become more complex, nurses are faced with environmental and emotional challenges. Some areas are more stressful to work in than others. A Pediatric Intensive Care Unit (PICU) can be a stimulating and rewarding place to work, but this setting also can be very emotionally difficult (Meadors & Lamson, 2008). Nurses who work in intensive care settings are at high risk for compassion fatigue (CF), secondary traumatic stress (STS), and ultimately nursing burnout (Meadors & Lamson, 2008). CF, STS and burnout can cause decreased productivity, decreased job satisfaction, and increased turnover for nurses resulting in increased healthcare costs and negative patient outcomes (Adwan, 2014). Research suggests interventions aimed at building resilience can mitigate the effects of CF, STS and burnout (Cocker & Joss, 2016).

CF is often described as the cost of caring. The term CF is frequently used synonymously with STS, which is described as the stress one experiences from caring for a person who has suffered from a traumatic event (Sorenson, Bolick, Wright, & Hamilton, 2016). Stamm (2010) notes that compassion fatigue has two aspects, burnout (exhaustion, anger, frustration, depression) and STS. STS occurs when healthcare providers are repeatedly exposed to patients' suffering from trauma or devastating illnesses and can ultimately lead to nursing burnout. Nurses who work in a PICU may be at an even higher risk for CF as advances in medical technology have allowed children to live longer and with more complex chronic conditions (Meadors & Lamson, 2008). Pediatric nurses are exposed to repeated patient suffering and death and experience the emotional responses from parents to their children's illness (Berger, Polivka, Smoot, & Owens, 2015).

CF can cause physical health issues for nurses including lack of energy, anxiety, inability to sleep, depression, and burnout. CF may also result in decreased productivity, decreased employee engagement, and

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increased turnover for nurses (Berger et al., 2015). Nurses suffering from CF often lack empathy for their patients and find it difficult to find satisfaction in their job (Adwan, 2014).

Understanding how CF contributes to nursing burnout and developing interventions to improve compassion satisfaction, build resilience, and reduce nursing burnout and turnover is important. Compassion satisfaction is “about the pleasure you derive from being able to do your work well” (Stamm, 2010, p. 12). Resilience is “a concept that proposes a recurrent human need to weather periods of stress and change successfully throughout life. The ability to weather each period of disruption and reintegration leaves the person better able to deal with the next change” (Resilience, 2009). Individuals with high compassion satisfaction and resilience are less likely to suffer from CF and burnout (Stamm, 2010).

The literature supports strategies aimed at promoting compassion satisfaction and resilience. CF education can have a positive effect on reducing CF. A systematic review of CF interventions targeted towards healthcare workers illustrated that interventions focused on providing education and improving resilience appeared to have the most impact on reducing CF (Cocker & Joss, 2016). Zadeh, Gamba, Hudson, and Wiener (2012) performed a quality improvement study evaluating the effectiveness of a wellness program for pediatric nurses. The researchers found that a 10 session wellness program was identified as very helpful and >75% of the participants noted that the education would positively change the way they performed their current job.

According to current literature, education on CF, burnout and compassion satisfaction can reduce CF and burnout and improve compassion satisfaction. This can result in higher levels of job satisfaction and less burnout (Cocker & Joss, 2016). Participants who reported higher compassion satisfaction were less at risk for CF and burnout (Meyer, Li, Klaristenfeld, & Gold, 2015; Stamm, 2010). Adwan (2014) suggested that interventions aimed at helping pediatric nurses identify and deal with grief could mitigate the grief nurses suffer from a patient death and improve job satisfaction. Pediatric providers who participated in an educational seminar on CF reported improved knowledge of stress reduction techniques and more feelings of peace and calmness (Meadors & Lamson, 2008). The purpose of this study was to evaluate the impact of a staff resilience program that included some educational components, in a PICU on Professional Quality of Life (ProQOL), to include CF, burnout, and compassion satisfaction, in addition to the impact on employee engagement and nursing turnover. The resilience program was developed and implemented by an interdisciplinary team, to include the Nurse Manager, Assistant Nurse Manager, Unit Educator, Chaplain, Child Life Therapist, and specific unit registered nurses.

Methods

Resilience program

A retrospective pre-test and post-test design was used in this study. The Pediatric ICU staff resilience program consisted of education to every RN in the PICU regarding CF, STS, burnout, and staff resilience. In addition, training was provided based on the American Association of Critical Care Nurses (AACN) six standards for a healthy working environment (skilled communication, meaningful recognition, appropriate staffing, true collaboration, effective decision making, and authentic leadership) (AACN, 2016). Staff resilience strategies included formal and informal debriefings, art, music, and pet therapy. Informal debriefings were offered every other month through breakfast with the chaplain. Twice a year, a formal ethical debriefing led by a trained pediatric ethicist was offered. Art and music therapy interventions were alternated every other month. Art therapy interventions included a variety of crafting options, making sugar scrubs and bath bombs. Music therapy was led by staff volunteers and included singing and playing of instruments in the nursing stations. Pet therapy was provided to the staff by child life once a week. A private Facebook page was developed for the staff on the unit. The Facebook page was used for communication, celebrations, and information on upcoming staff resilience activities. Lastly, monthly celebrations occurred during heart month (February) and critical care awareness month (May). Unit t-shirts were designed and available for staff to purchase. In addition, a wide variety of activities were offered throughout the months including contests, photo booths, and ice cream socials. Prior to the implementation of the staff resilience program, there were no formal methods in the department addressing burnout and resilience.

Setting and sample

The study was based in a 34 bed PICU in a children's hospital located within the south central part of the United States. The hospital offers specialized care in cardiac surgery, cardiology, oncology, neurology, neurosurgery, and is a level one trauma center. Inclusion criteria for the study included all RN's who worked in the PICU as of January 2018 who had been working in the PICU for a minimum of three months ($N = 150$).

Procedures

Approval for this study was obtained through an affiliated university Institutional Review Board and the organization's Office of Research. Employee engagement, using six Press Ganey employee engagement items, was measured in 2016 prior to implementation of the resilience program and again during the first 3 months of 2018. The scale consisted of the six Likert scale items (1–5) with higher numbers indicating a positive response. An example was: “I am proud to tell people I work for this organization”. RN turnover results from 2016 were compared to RN turnover for 2017. In addition, an evaluation of CF (STS and burnout) and compassion satisfaction was assessed post implementation during the first 3 months of 2018 using the Professional Quality of Life (ProQOL) Scale (Stamm, 2010). The ProQOL is commonly used to measure the impact of helping individuals who experience suffering and trauma and has demonstrated reliability and validity in multiple published studies. The instrument has subscales for compassion satisfaction and compassion fatigue which includes two components, STS and burnout (ProQOL.org, 2012; Stamm, 2010).

Data collection

Data for this study was obtained either electronically using an employee survey or from Human Resources. RN turnover data and 2016 employee engagement scores were requested and provided by the organization's Human Resources Department. Research electronic data capture (Harris et al., 2009; REDCap, 2004) was used to administer the ProQOL and the 2018 employee engagement survey.

Data analysis

Descriptive statistics, including frequency distributions and means were used to describe the demographic characteristics of the participating RN's. All analyses were conducted using SPSS version 22; an alpha level of 0.05 was used to determine statistical significance. Correlations between education level and experience were assessed for impact on CF, STS, burnout, compassion satisfaction and engagement using Spearman's Rho. Pearson's correlation was used to evaluate relationships between CF, STS, burnout, and compassion satisfaction. A *t*-test was used to determine statistical significance of impact of program on RN turnover and engagement.

Results

Over 90% of the nurses held a Bachelor's degree in Nursing or higher (9% Associate; 87% BSN; 4% MSN). Approximately two-thirds of

respondents (68%) had five years or less experience as a nurse (<1, 30%; 1–5, 38%; 5–10, 7%; >10, 25%).

RN turnover and employee engagement scores improved as an outcome of the resiliency program. RN turnover was reduced during the implementation year of the staff resilience program by 6%, although the decrease in turnover was not statistically significant ($p = .22$). In addition, employee engagement scores ($n = 82$ pre-intervention compared to $n = 75$ post-intervention) increased from a mean score of 4.15 to 4.18, but that change was not a statistically significant improvement ($p = .67$).

Evaluation of the aggregate ProQOL scores ($n = 70$) were encouraging. CF (STS and burnout aggregate scores) were low, while compassion satisfaction scores were high. The average STS score was 20.4 (see Table 1). Burnout scores averaged 21.7. Inversely, the average score among participants for compassion satisfaction was 42.6. There was a statistically significant positive correlation between compassion satisfaction and engagement ($r = 0.45$; $p < .001$). Additionally, there was a statistically significant positive correlation between years of experience and engagement ($r = 0.27$; $p = .018$) and years of experience and compassion satisfaction ($r = 0.29$; $p = .015$), suggesting that as years of experience increased so did compassion satisfaction and engagement (Table 2). A statistically significant negative correlation was found between engagement and burnout ($r = -0.44$; $p < .001$), indicating that as burnout increased engagement decreased. The same was true for engagement and STS ($r = -0.34$; $p = .004$); as STS increased, engagement decreased. There was also a statistically significant negative correlation between compassion satisfaction in comparison to STS ($p = .024$) and burnout ($r = -0.62$; $p < .001$) indicating that as compassion satisfaction increased, burnout and STS decreased. Finally, there was a statistically significant positive correlation between STS and burnout ($r = 0.50$; $p < .001$) suggesting that as STS increased so did burnout.

Discussion

The results of this evaluation suggested that a staff resilience program can be an effective intervention to mitigate compassion fatigue, STS and reduce burnout in PICU nurses. Reducing compassion fatigue is important to prevent nursing turnover and improve employee engagement. Nursing turnover is costly to organizations and disengaged employees can have a negative impact on the delivery of quality care and patient satisfaction. Compassion satisfaction can mitigate the effects of CF resulting in reduced burnout (Stamm, 2010). A 6% reduction in RN turnover and an increase in employee engagement was noted as an outcome of the resilience program, but the results were not statistically significant. However, when comparing the aggregate results of the ProQOL, the RN's scored low in STS (20.4) and burnout (21.7) and high for compassion satisfaction (42.6). STS and burnout scores totaling <22 indicate low levels of STS and burnout respectively. Compassion satisfaction scores >42 equal high levels of compassion satisfaction, while scores between 23 and 41 are average (Stamm, 2010). Reducing burnout and improving compassion satisfaction are important for the organization, as well as the mental health of the nurses (Berger et al., 2015). These results supported past studies that have shown staff resilience education/strategies can result in less CF and burnout and improve compassion satisfaction (Cocker & Joss, 2016).

There was a statistically significant, moderately high negative correlation between compassion satisfaction and burnout, suggesting that as compassion satisfaction increased burnout was reduced. There was also a statistically significant positive correlation between compassion satisfaction and engagement indicating those employees who have high compassion satisfaction also appear to be more engaged employees. The positive correlation between years of experience and higher levels of engagement and compassion satisfaction may indicate that employees with high compassion satisfaction are more likely to stay; employees with low levels of compassion satisfaction likely suffer from more STS and burnout and therefore may be more likely to leave the organization.

Table 1
Aggregate ProQOL scores ($N = 70$).

	Mean	SD	Interpretation of results
Secondary traumatic stress	20.4	5.2	Low
Burnout	21.7	4.4	Low
Compassion satisfaction	42.6	3.9	High

Table 2
Correlations ($N = 70$).

	Engagement	Compassion satisfaction	Burnout	STS
Years of experience	0.27* 0.018	0.29* 0.015	−0.22 0.074	−0.03 0.807
Engagement		0.45** <0.001	−0.44** <0.001	−0.34* 0.004
Compassion Satisfaction			−0.62** <0.001	−0.27* 0.024
Burnout				0.50** <0.001

Note: Cells contain correlation coefficient in the top row and associated p-value r (p) on the second row.
* Indicates statistical significance $p < .05$.
** Indicates statistical significance $p < .001$.

These results are important for organizations to consider when implementing interventions to support PICU nurses and reduce RN turnover. The results from the ProQOL indicate a staff resilience program can have a positive impact on pediatric intensive care nurses and support other clinical studies that have shown as compassion satisfaction increase, CF and burnout decrease (Stamm, 2010). Additionally, education on CF, STS and burnout can be an effective method to reduce these feelings (Zadeh et al., 2012).

Limitations

Limitations to this study include the time frame of evaluation. The program was implemented in 2017, and the evaluation of engagement, CF and compassion satisfaction occurred in early 2018. It would have been helpful to have a pre and post comparison of the ProQOL scores, rather than only the post evaluation. In addition, this was a single center study with convenience sampling. Employee engagement scores for this department were already above the national average before the implementation of the program. Lastly, RN turnover was evaluated during the intervention period; therefore, it is unclear if the program had a sustained impact on turnover.

Conclusion and implications for practice

CF and burnout are prevalent in ICU nurses, as well as pediatric nurses. While there seems to be strong agreement in the literature that compassion fatigue and burnout exist in intensive care nurses (Cocker & Joss, 2016), there are very few studies specific to the pediatric environment. The literature supports education on compassion fatigue (Meadors & Lamson, 2008), but it is unclear which resilience building interventions make a difference. There were no reported negative consequences to the implementation of the staff resilience program in the setting for this study, and the results indicated that education and interventions were helpful in reducing CF and improving compassion satisfaction. It seems prudent that organizations and nursing leaders should provide education and interventions to pediatric intensive care nurses regarding CF/STS, burnout, and compassion satisfaction/resilience. This includes the definitions of each, symptoms, and interventions that promote compassion satisfaction/resilience.

CF and burnout can have negative consequences for the nurse, the patients they are caring for, and the organization leading to negative

physical symptoms for the nurse, decreased job productivity, decreased employee engagement, increased turnover, and burnout. The results of this study illustrated that years of experience was associated with compassion satisfaction, or joy in your work, and higher work engagement. This was a positive finding in relation to the nursing workforce, since nurses who are happy are more likely to work more years. Additionally, we know that environments where nurses are more satisfied and engaged have improved patient satisfaction. Future research needs to be focused around using standardized tools to measure CF, compassion satisfaction, and resilience as well as specific interventions for pediatric intensive care nurses. Longitudinal studies would be helpful to determine the sustainability of the results over time. An assessment of the emotional health of nurses in the work environment, using an instrument such as the ProQOL scale, would offer important information for healthcare leaders. Healthcare organizations should focus on providing resilience building interventions in high stress environments like the PICU, to promote compassion satisfaction and decrease CF among nurses what work in the environments.

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CRediT authorship contribution statement

Stacy Flanders: Conceptualization, Methodology, Writing - original draft, Writing - review & editing, Visualization, Project administration. **Debra Hampton:** Methodology, Writing - review & editing, Visualization, Supervision. **Pam Missi:** Writing - review & editing. **Charlotte Ipsan:** Writing - review & editing. **Cis Gruebbel:** Writing - review & editing.

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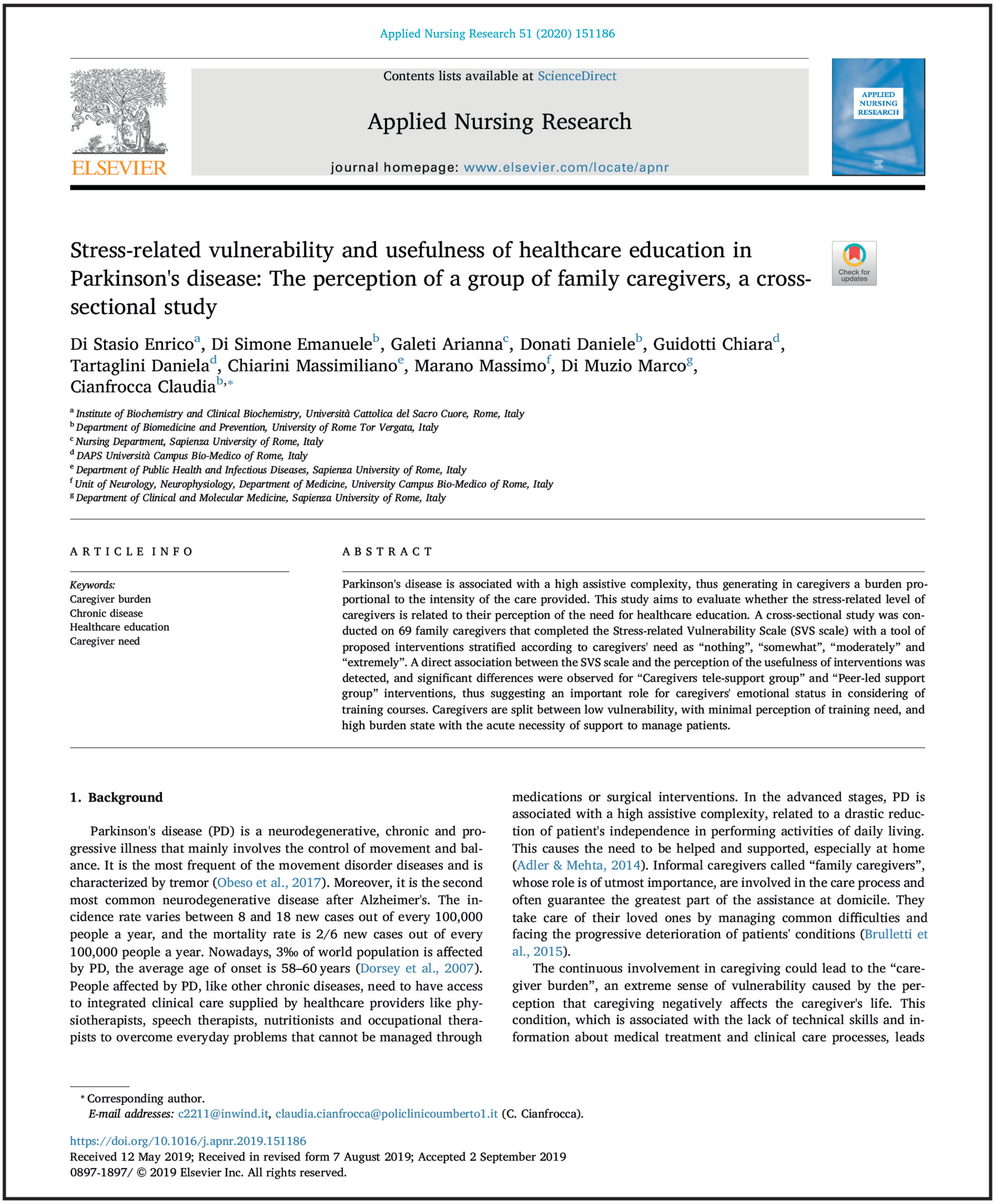

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Stress-related vulnerability and usefulness of healthcare education in Parkinson's disease: The perception of a group of family caregivers, a cross-sectional study

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ABSTRACT

Parkinson's disease is associated with a high assistive complexity, thus generating in caregivers a burden proportional to the intensity of the care provided. This study aims to evaluate whether the stress-related level of caregivers is related to their perception of the need for healthcare education. A cross-sectional study was conducted on 69 family caregivers that completed the Stress-related Vulnerability Scale (SVS scale) with a tool of proposed interventions stratified according to caregivers' need as "nothing", "somewhat", "moderately" and "extremely". A direct association between the SVS scale and the perception of the usefulness of interventions was detected, and significant differences were observed for "Caregivers tele-support group" and "Peer-led support group" interventions, thus suggesting an important role for caregivers' emotional status in considering of training courses. Caregivers are split between low vulnerability, with minimal perception of training need, and high burden state with the acute necessity of support to manage patients.

1. Background

Parkinson's disease (PD) is a neurodegenerative, chronic and progressive illness that mainly involves the control of movement and balance. It is the most frequent of the movement disorder diseases and is characterized by tremor (Obeso et al., 2017). Moreover, it is the second most common neurodegenerative disease after Alzheimer's. The incidence rate varies between 8 and 18 new cases out of every 100,000 people a year, and the mortality rate is 2/6 new cases out of every 100,000 people a year. Nowadays, 3‰ of world population is affected by PD, the average age of onset is 58–60 years (Dorsey et al., 2007). People affected by PD, like other chronic diseases, need to have access to integrated clinical care supplied by healthcare providers like physiotherapists, speech therapists, nutritionists and occupational therapists to overcome everyday problems that cannot be managed through medications or surgical interventions. In the advanced stages, PD is associated with a high assistive complexity, related to a drastic reduction of patient's independence in performing activities of daily living. This causes the need to be helped and supported, especially at home (Adler & Mehta, 2014). Informal caregivers called "family caregivers", whose role is of utmost importance, are involved in the care process and often guarantee the greatest part of the assistance at domicile. They take care of their loved ones by managing common difficulties and facing the progressive deterioration of patients' conditions (Brulletti et al., 2015).

The continuous involvement in caregiving could lead to the "caregiver burden", an extreme sense of vulnerability caused by the perception that caregiving negatively affects the caregiver's life. This condition, which is associated with the lack of technical skills and information about medical treatment and clinical care processes, leads

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the caregivers to perceive some needs (Zarit, Todd, & Zarit, 1986). Moreover, as stated in the literature, there is a link between the needs perceived by caregivers of PD patients and the unpredictability of the motor and non-motor symptoms of the disease, the care-receiver's degree 50 of disability, the progress of the disease, the number of hours of assistance a day and the duration of the illness. The most mentioned need by caregivers is acquiring adequate training about the evolution of the disease and the management of the symptoms and emotions at home (Grun, Pieri, Vaillant, & Diederich, 2016; Ashrafian, Feizollahzadeh, Rahmani, & Davoodi, 2018; Chiarini et al., 2017; Eluvathingol Jose & Portillo, 2013; Boersma et al., 2017).

A study conducted in 2015 by Lageman et al. showed that the global distress of PD caregivers does not correlate with patient's disability and the need for support is always perceived from the moment of diagnosis onwards (Lageman, Mickens, & Cash, 2015).

On the other hand, a review conducted in 2014 focused on caregivers of people affected by PD and highlighted that the burden is directly proportional to the intensity of the assistance provided (hours a day) (Bhimani, 2014). Having the possibility of taking part in training classes to manage PD symptoms at home or giving this opportunity to the patient could decrease the burden level of both caregivers and care-receivers, and a sound training might prevent the sense of incompetence, anxiety, depression and insomnia, which negatively affect caregivers' quality of life and health (Bhimani, 2014; Boersma et al., 2017; Udow et al., 2017).

Together with all the healthcare professionals who work in favour of patients affected by PD and their caregivers, nurses play a pivotal role in the daily management of patients as they are the agents of change and improvement in care pathway. Nursing staff spends most of the time at patients' side during hospitalization, and the attitude of these professionals to empathy encourages patients and familial caregivers to express their needs on which are based personalized healthcare plans. Moreover, their support and training awake caregivers' educational needs, improve their confidence and help them in understanding the importance of their role (Fernandes & Angelo, 2016).

The key role of family caregivers and the importance of their training is a topic treated in literature. Some studies showed the importance of the individualized training done by nurses specialized in Parkinson' disease. They highlighted both the ability in understanding the disease and all the fundamental aspects that impact on the patient's daily life, and in acquiring the competencies to manage the patient at home properly (Hellqvist & Berterö, 2015; Kuo et al., 2017).

Others highlighted the positive support that online and telematics training courses can give to caregivers, reducing anxiety and depression. Educational instantaneous interventions done through electronic devices gave the opportunity to create a strong collaborative relationship with healthcare professionals and simultaneous classes helped caregivers that could share their emotions (Blom, Zarit, Groot Zwaaftink, Cuijpers, & Pot, 2015; Shah et al., 2015).

Finally, other researches pointed out the effectiveness of training in theoretical and practical courses during which caregivers could learn and acquire technical skills and even share their opinions and experiences of caregiving, thus generating a decrease of burden levels (Abendroth, Greenblum, & Gray, 2014; Cianfrocca et al., 2018; Habermann & Davis, 2006; Katsuki et al., 2011; Zingaretti, 2011).

However, even though the topic of caregiver's training is widely explored in literature, the role of stress vulnerability on PD patients' caregivers' perceptions regarding the usefulness of training courses and the advantages of such interventions on their quality of life have not been explored yet.

2. Aim

This study aims to evaluate whether the stress level of familial caregivers of Parkinson's disease patients is related to their perception of the need and usefulness of healthcare education.

3. Materials and methods

3.1. Design

A cross-sectional study involving familial caregivers of patients affected by Parkinson's disease was conducted from July to September 2017.

3.2. Study sample and inclusion and exclusion criteria

69 family caregivers were voluntarily enrolled during the bimonthly visits with the neurologist at the neurologist office into an Italian Polyclinc. Inclusion criteria were: a) age higher than 18 years old and b) being the familial caregiver of Parkinson's disease patients suffering from Parkinson's disease at stage 2.5 / 3, with Montreal Cognitive Scale (MoCA) > 24.

3.3. Tools and data collection

The study was conducted and then reported according to the STROBE checklist. Sociodemographic data were assessed through a questionnaire. Moreover, each participant was asked to answer two different questionnaires. The first is the Stress-related Vulnerability Scale (SVS scale) an Italian tool, created and validated in Italy in 2010 and used to measure the vulnerability related to stressful events and situations, like being a familial caregiver and the lack of support received (Tarsitani, Battisti, Biondi, & Picardi, 2010).

The SVS Scale is a self-completed questionnaire that considers “the last month” as a reference period and gives an overall score that indicates a growing measure of stress-related vulnerability. The overall score is obtained from the sum of the scores extracted from the answers given to each single item of the scale. The tool was built on the basis of the scientific literature concerning the measurement of stress and social support. The version used in this study was obtained from a selection of the items of other previous versions, chosen according to the psychometric characteristics. During the process of validation the SVS was administered twice to a non-clinical sample of 202 subjects together with validated tools for stress and social support measurement as the Perceived Stress Scale created by Cohen, Kamarck, and Mermelstein (1983)), and the Multidimensional Scale of Perceived Social Support created by Zimet, Dahlem, Zimet, and Farley (1988). The homogeneity and reliability of the SVS re-test test were satisfactory, the subscales have shown a good convergent validity with the other scales mentioned above and already validated for the measurement of subjective stress and social support. Moreover, the SVS showed a sensitivity to change, with a significant association between changes in the total score and life events occurring in a six-month interval between two evaluations (Tarsitani et al., 2010). The scale consists of 9 items scored on a 4-point Likert scale. Three score ranges have been fixed according to the three different vulnerability levels:

From 0 to 10 points: normal vulnerability level (Normal SVS); it indicates a stress-related vulnerability that falls within the normal range or in any case does not seem to represent a significant risk factor for the state of health.

From 11 to 18 points: significative vulnerability level (Significative SVS); it indicates a level of vulnerability above the average that may pose a significant risk of future health problems.

From 18 to 27 points: high vulnerability level (High SVS); it indicates significant levels of tension and demoralization, often associated with poor interpersonal support. This score allows to identify people who could benefit from targeted supportive interventions.

The second tool is a self-assessed questionnaire created “ad hoc” according to the existing literature that proposes five specific nursing educational interventions aimed at caregiver training and support. During the survey the opinion of the participants about the usefulness of these proposed interventions was asked to understand whether a

higher level of stress is related to a higher consideration of the usefulness of the proposed interventions.

The tool is composed of the five proposed interventions:

- Intervention n°1: Supporting and training interventions provided by nurses specializing in Parkinson's disease (Hellqvist & Berterö, 2015); (Int. 1: S&T).

- Intervention n°2: Psychoeducational and skill training (how to preserve health, how to take care of the care-receiver, how to get information about the disease) interventions for caregivers provided by qualified nurses (Habermann & Davis, 2006); (Int.2: PST).

- Intervention n°3: Caregivers tele-support groups led by nurses specializing in caregiver education (Shah et al., 2015); (Int.3: TSG).

- Intervention n°4: Peer-led support groups among caregivers of people with Parkinson's disease aimed at sharing mutually personal experiences, socializing and exchanging advice (Abendroth et al., 2014); (Int.4: PLG).

- Intervention n°5: Multidisciplinary classes led by medical and nursing staff aimed at providing caregivers with a practical aid to improve their care activity (Zingaretti, 2011); (Int.5: MCS).

For each intervention, the possible answers were scored on a 4-point Likert scale and a "total interventions score" parameter, ranging from 0 (each intervention answer as "Nothing") to 15 (each intervention answer as "Extremely") was created, adding together the scores of each intervention.

3.4. Statistical analysis

Statistical analysis was performed by using the Statistical Package for Social Science (SPSS), release 15.0. Categorical variables were expressed as frequencies and the X2-test was used to assess the significance of the differences between subgroups; standardized residual analysis was performed to locate the significant different subgroup frequency. Moreover, to determine the relevance of the observed frequency differences, the effect size (w) of each comparison was calculated. A probability of < 0.05 was considered statistically significant.

Ethical approval

The aim of the study was explained during the enrolment by the neurologist and was even written upon informed consent. Each participant could answer the questionnaires anonymously.

4. Results

In Table 1, the demographical parameters of the population under study stratified according to SVS classes are reported. Seventy-one percent of the sample is composed of females and 72% is over the age of 60. No significant differences were detected in the frequency distribution of gender, age, kinship, education and marital status among SVS subgroups. Concerning the proposed interventions, specific profiles of distribution were observed for total addressed intervention priority (total interventions score) as a function of SVS classes ($p = 0.060$, $w = 0.30$ corresponding to a "medium" effect). A high frequency of low score answers is evident in Normal and Significative SVS subgroups (39% and 56% of score 0–3, respectively). The proportions constantly decrease as the total score increases down to 19% and 25% at 12–15 total score, respectively. On the other hand, the frequency of High SVS subgroup progressively rises from 6% at 0–3 to 56% at 12–15 total score (Fig. 1). Table 2 reports the distribution of each proposed intervention (Int. 1: S&T; Int.2: PST; Int.3: TSG; Int.4: PLG; Int.5: MCS) in SVS subgroups. Significant differences in class frequency were observed for "Int.3: TSG" and "Int.4: PLG" ($p = 0.034$, $w = 0.31$-"medium", and $p = 0.048$, $w = 0.30$-"medium", respectively) and located in "Extremely" answers in High SVS subgroup for intervention 3 and in "Extremely" and "Nothing" answers in High and Normal SVS subgroups, respectively, for intervention 4. A significance of 0.134 ($w = 0.27$-small), 0.064 ($w = 0.29$-small) and 0.095 ($w = 0.28$-small) was measured for interventions 1, 2 and 5, respectively.

Finally, considering the answer profiles according to SVS classes, a recurrent decrease and increase between Normal and High SVS (in total and each specific intervention) were observed of "Nothing" and "Extremely", respectively. A mixed pattern was detected for "Somewhat" and "Moderately" answers.

5. Discussion

Supporting PD patients' familial caregivers represents an important task for the nursing profession. Parkinson's disease negatively affects both patients' and caregivers' lives. Familial caregivers assure almost 80% of the care provided to chronic patients, and high levels of caregiving can cause discomfort symptoms like depression, anxiety and sleep disturbances, leading to the caregiver burden (Naiditch, Triantafillou, Di Santo, et al., 2013; Nobili, Massaia, Isaia, et al., 2011; Torny, Videaud, Chatainier, Tarrade, & Meissner, 2018).

One of the main causes of burden is that family caregivers feel insufficiently trained even in the basic activities of daily living and, therefore, unprepared to undertake the tasks of caregiving (Grün, Pieri, Vaillant, & Diederich, 2016; Morley et al., 2012; Raccichini et al., 2015). The most mentioned need expressed by caregivers is to acquire adequate training about the evolution of the disease and the management of the symptoms at home (Eluvathingol Jose & Portillo, 2013). Even though training is considered one of the most important interventions to help caregivers, only a few studies have treated this theme by considering the PD patient caregivers' perception, the role of caregiver stress-related vulnerability, and their assessment of the effectiveness of healthcare educational programs. In the present manuscript, the perception of the usefulness of the five specific proposed interventions has been studied considering the SVS scale levels. A direct association between SVS scale levels and the perception of the usefulness of the nursing interventions can be detected, thus suggesting an important role of caregivers' emotional status in considering training courses. "Extremely" answers are always higher than 43% in the subjects belonging to High SVS subgroup. On the other hand, the mean frequency of "Nothing" answers is 40% in Normal SVS subjects; a mixed profile is observed in the Significant SVS subgroup. Moreover, even though the recruited subjects are equally split into SVS subgroups (31, 36 and 33%, respectively), "Nothing" and "Extremely" options represent 35% and 28%, whereas "Somewhat" and "Moderately" answers

Table 1
Demographical parameters of the population under study.

	Population under study (n = 69)	Normal SVS	Significative SVS	High SVS	p
Gender (male/female) (%)	29 / 71	38 / 62	28 / 72	22 / 78	0.485
Age (30–60/ > 60 yrs)	28 / 72	29 / 71	40 / 60	13 / 87	
Kinship (cs/pr/sn/br)	78/7/12/3	81/5/10/5	80/8/12/–	74/9/13/4	
Education (el/sc/hs/g)	7/32/73/13	5/33/43/19	8/28/52/12	9/35/48/9	
Marital status (um/mr/ch/dv/wd)	15 /71/4/4/4	10/76/–/5/10	16/72/4/–/8	17/65/9/9/–	

Legend: cs = consort, pr = partner, sn = son, br = brother, el = elementary, sc = secondary, hs = high school, gr = gradutation, um = unmarried, mr = married, ch = cohabitant, dv = divorced, wd = widower.

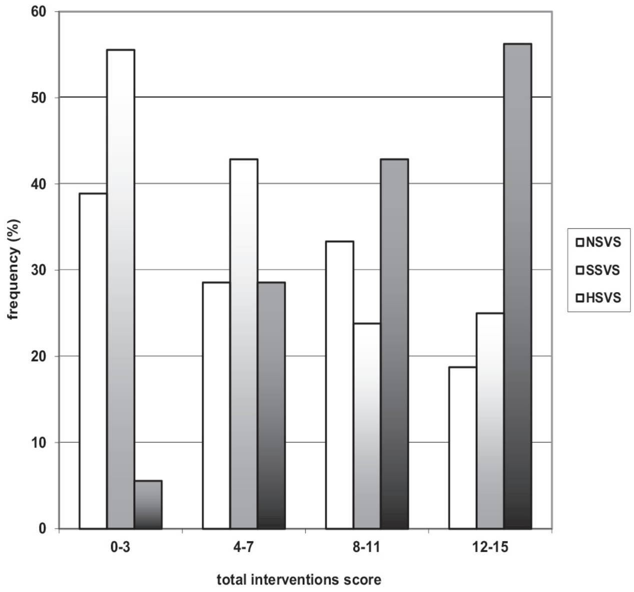

Fig. 1. SVS classes' frequency (%) distribution in quartiles total intervention score. A decrease of Normal/Significative and an increase of High SVS class frequency can be observed as the total score raises. (p = 0.060.)

Table 2
Frequency distribution (%) of responses to each specific intervention in different SVS subgroups.

	Normal SVS (%)	Significative SVS (%)	High SVS (%)	p
Supporting and training interventions				
Nothing	52.4	36.0	17.4	0.134
Somewhat	14.3	20.0	21.7	
Moderately	9.5	28.0	17.4	
Extremely	23.8	16.0	43.5	
Psychoeducational and skill training				
Nothing	23.8	36.0	13.0	0.064
Somewhat	23.8	32.0	21.7	
Moderately	19.0	16.0	4.3	
Extremely	33.3	16.0	60.9	
Caregivers tele-support groups				
Nothing	42.9	56.0	34.8	0.034
Somewhat	19.0	24.0	8.7	
Moderately	28.6	8.0	13.0	
Extremely	9.5	12.0	43.5	
Peer-Led support groups				
Nothing	42.9	28.0	4.3	0.048
Somewhat	9.5	20.0	21.7	
Moderately	19.0	32.0	21.7	
Extremely	28.6	20.0	52.2	
Multidisciplinary classes				
Nothing	38.1	32.0	21.7	0.095
Somewhat	14.3	20.0	17.4	
Moderately	23.8	28.0	4.3	
Extremely	23.8	20.0	56.5	

reach only 19% each of total answers, respectively.

Therefore, caregivers seem to switch between two major conditions: low vulnerability level, with the minimal perception of training need and high burden state with the impending necessity of support to manage PD patients. Therefore, in the population under study, caregivers' vulnerability seems to be equally distributed in the three SVS levels, and the perception of receiving nursing educational interventions as very useful is directly related to the increase of burden level. Moreover, what clearly emerges from the study is the need of sharing experiences that is associated to the stress levels of caregivers. In fact significant differences were detected in the estimated usefulness of the interventions 3 "Caregivers tele-support groups" and 4 "Peer-led support groups among" according to the stress levels of caregivers and these interventions are referred to the opportunity to share experiences and emotions.

6. Limits

This study has some limitations. The first limit is represented by the small number of the population under study (n = 69). Moreover, the survey could help in understanding the perception of the usefulness of the proposed interventions, but no question investigated whether caregivers had ever attended courses like the ones proposed. Furthermore, a timing evolution of caregiver's burden level and training need should be traced to detect the incidence of increasing periods of stressing condition on the perception of assistance and help requirement. Another limit is that it is not possible to correlate the results with the severity of the patient's illness, as there is no available data.

Another data missing is about both patients' and caregivers' illnesses and comorbidities. The tool used to assess caregiver vulnerability represents another limit. The SVS scale is not created and based on caregivers of PD patients; no tool like this exists as of now. So it is necessary to adapt the existing tools to this particular category of caregivers.

7. Conclusion

The usefulness of healthcare education addressed to familial caregivers in Parkinson's disease cases emerges from the existing literature. It could lead to an enhancement of the quality of life of both patients and caregivers. However, this article deals with a broad issue that needs to be further deepened through additional focused research as it treats a theme not sufficiently explored.

The stress-related vulnerability seems to be related to the perception of the usefulness of the interventions proposed. What emerges is that, probably, the more you are stressed and involved in care management at home, the more you need to be helped.

Moreover, it could be supposed that the lack of positive perception about educational support is due to a lack of awareness of the progression of the pathology or to a partial involvement in the care process. However, further studies about this topic should be conducted, first by increasing the sample size and even by correlating the stress-related vulnerability with the perception of the usefulness of the educational support, patients' clinical conditions and the number of hours of care actually delivered by the caregiver at home. Finally, the importance of the evolution of help-need perception related to the progress in time of the caregiver's burden and the care-receiver's disease progression should be pointed out.

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Declaration of competing interest

The author(s) declare no potential conflict of interest concerning the research, authorship, or publication of this article.

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“It's up to me with a little support” – Adherence after myocardial infarction: A qualitative study

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ABSTRACT

Background: Ischemic heart disease and stroke remain the leading causes of death globally. Poor adherence to treatment amongst patients with chronic health conditions is a global unresolved problem of enormous magnitude. Despite extensive research in the field of adherence behaviors, few studies have focused on motivational aspects that can enhance adherence from the patients' points of view post myocardial infarction.
Aim: To gain insights into the perceptions that underline health-related adherence behaviors, from the perspective of patients who experienced a heart attack.
Design: A phenomenological approach.
Methods: The study used a content analysis method, with qualitative criteria to establish trustworthiness. Interviews were conducted with a purposive sample of 22 participants post myocardial infarction, recruited from a hospital cardiac rehabilitation program and communities in Northern Israel.
Results: The abstraction process generated two main categories and six sub-categories imbedded in the Self Determination Theory framework. While inner self determination or willpower, as expressed by the participants, was perceived as the most crucial motivator, it was insufficient. A sense of self competency and the ability to tailor life changes, according to personal preferences, is needed to turn willpower into practice. Extrinsic motivators such as family members, especially spouses and health professionals, are important to strengthen intrinsic motivation. Attitudes of caring, respect for values, and autonomy as opposed to patronization were perceived as helpful. The benefits of a cardiac rehabilitation program were articulated by attendees of the program in contrast to excuses by non-attendees
Conclusion: Understanding adherence as a complex holistic phenomenon could advance theoretical insights and enhance adherence to therapies and healthy lifestyle among people post myocardial infarction.
Impact: Study findings may advance the self-care of people with long-term health conditions, and assist professionals to conduct interventions that strengthen adherence. Increased adherence can impact life expectancy, quality of life, and reduce the economic burden on health care systems and societies.

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What is already known about the topic?

- Adherence to long-term therapies is approximately 50% in developed countries and lower in low and middle-income countries.
- Poor adherence of people with chronic diseases leads to mortality, morbidity, poor quality of life and increased economic burden on health care systems.
- Despite the large number of variables that were identified as related to adherence, not much has been understood that increases adherence behaviors.

What this paper adds

- Non-adherence is a complex holistic phenomenon that cannot be resolved by addressing single attributes such as increasing health literacy.
- Families and healthcare providers can strengthen motivation, willpower and self-competency by respecting personal preferences and autonomy.
- Health care practitioners should establish tailored plans of care, in cooperation with patients, rather than dictate medical instructions for patients.

1. Introduction

Poor adherence to treatment amongst patients with chronic health conditions is a global unresolved problem of enormous magnitude. Adherence is defined by the WHO (World Health Organization) report as “the extent to which a person's behavior – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider.” (Sabaté et al., 2003, p. 3). The report estimates adherence to long-term therapies is approximately 50% in developed countries, assuming much lower adherence in low and middle-income countries.

A recent US study on five lifestyle risk factors (smoking, BMI, physical activity, diet and alcohol intake) revealed a significantly prolonged life expectancy at age 50 (14 years for men and 12.2 years for women) among those with healthy lifestyle habits (Li et al., 2018). Worldwide, poor adherence in growing populations with chronic diseases leads to mortality, morbidity, poor quality of life, and creates an immense economic burden on health care systems and societies (Bansilal et al., 2016; Kotseva et al., 2017; Sabaté et al., 2003).

Ischemic heart disease and stroke are the world's biggest killers, accounting for a combined 15.2 million deaths in 2016. These diseases have remained the leading causes of death globally in the past 15 years (World Health Organization, 2018). Mortality rates for acute myocardial infarction (MI) decreased substantially during the last four decades, due to significant advances in prevention and interventions (Wilson and Douglas, 2013). For example, most patients receive health behavior guidance after a cardiac event and referral to cardiac rehabilitation programs. Cardiac rehabilitation programs involve interventions such as physical activity counseling, exercise training, nutritional counseling, weight control management, lipid management, blood pressure monitoring, smoking cessation, and psychosocial management (Piepoli et al., 2010). In spite of guidance and rehabilitation programs, the tendency is for short-term adherence, diminishing in the subsequent 1–2 years to approximately 50% adherence (Crowley et al., 2015).

In Israel, MI is the second most common cause of death, accounting for 15% of mortality (Israeli Ministry of Health, 2018). In 2018, 79% of the Israeli population were Jews and 21% Arabs (85% of the Arabs were Muslims and the remainder Christians and Druze). There is still evidence of inequalities in health care in Israel among three population groups: non-Jews, people living in the periphery and among people with poor socioeconomic status. These characteristics are often correlated. Arabs have worse health status than Jews on many indicators, including heart diseases. North and south districts have higher mortality rates than central Israel. Regardless of ethnic origin, poor socioeconomic status is associated with poor adherence to treatment protocols and worse health outcomes (Colombo, 2012).

A health literacy survey was conducted in Israel among 600 adults randomly selected from a national database. Home interviews were conducted in Hebrew, Russian, and Arabic. Results indicated that income and years of education were significantly associated with health literacy, playing a key role in determining self-assessed health, beyond sociodemographic variables (Levin-Zamir et al., 2016). Identifying indicators that play a significant role in health disparities contribute to a better understanding of the problem and a basis for health promotion actions, further research, and health policy.

Numerous studies have investigated factors that facilitate or inhibit adherence among patients post MI. The different methodological approaches and methods make it difficult to compare findings. However, many attributes are known to be related to the phenomenon of adherence among people post MI, such as personal attributes, the role of family, and the role of health care providers.

1.1. Personal attributes and adherence

Middle aged (50–69 years) patients had higher adherence than oldest ($\geq$70 years) and youngest ($<$50 years) patients (Crowley et al., 2015; Kronish and Ye, 2013). Adherence is worse in patients with low education levels ($<$12 years of school) and health literacy (Crowley et al., 2015). Low socioeconomic status was also found to increase non-adherence to medication and smoking cessation (Campbell et al., 2014; Crowley et al., 2015; Jackevicius et al., 2008; Kronish and Ye, 2013).

Illness perceptions and health beliefs were found to play a role in patient self-care in qualitative studies, from being well, fully recovered and having a zest for life; to being ill with constant concerns, and uncertainty about the future (Bergman et al., 2009; Gregory et al., 2006). Feelings of anxiety, depression and threat of complications (e.g., recurrent MI or stroke) were found to be triggers for both adherence and non-adherence (Choudhry et al., 2014; Johansson et al., 2007).

Several studies identified variability in adherence in different ethnic and cultural groups (Fernandez et al., 2015; Groleau et al., 2010; Zhang et al., 2014). Zhang et al. (2014) found racial/ethnic differences in medication adherence among five American groups, with poorer adherence in minorities. The influence of culture was found in French Canadians who attributed spiritual meaning to the heart that shaped their myocardial infarction experience (Groleau et al., 2010).

1.2. The role of the family in adherence

Family relationships and support were identified as important driving forces, especially if family members shared the change in lifestyle. Patients without family, or who live alone or are socially isolated, are highly vulnerable to poor self-care. For example, dietary adherence was found to be poor among patients without supportive family and medication (Dunbar et al., 2008; Fernandez et al., 2015). On the other hand, relationships with family and friends can become strained after a myocardial event. For example, over-protective families and friends can prevent patients from performing important activities such as mild exercise (Roebuck et al., 2001), while more than one social gathering per week is a significant statistical predictor of non-adherence to diet (Ali et al., 2017).

1.3. The role of health care providers in adherence

A qualitative study with 35 participants recovering from MI explored which experiences would have helped them to adhere to a healthy lifestyle. A major finding was the desire for long-term follow up and support from health care practitioners. Participants emphasized the need for regular professional supervision, obtaining support and reassurance for themselves and their families, and cardiac rehabilitation classes with people who shared similar experiences (Gregory et al., 2006). Awareness of healthy lifestyle can be also raised in the public and community arena, including changes in food products at stores and restaurants, and using the media as change agents (Fernandez et al., 2015; Kronish and Ye, 2013).

Despite the proven effectiveness of self-care interventions, patient participation after MI is poor (Al-Mallah et al., 2016; Barnason et al., 2012; Giannuzzi et al., 2008). A randomized control trial on the effect of a supportive educational intervention found higher levels of self-care knowledge, motivation, and skills among patients after MI, compared to a baseline and control group (Mohammadpour et al., 2015). Barriers predicting poor participation in cardiac rehabilitation programs can be classified into person-related and program related. Personal factors included elderly, single, women, people with comorbidities, unemployed, less educated, lower income, and lack of motivation. Program related factors included accessibility barriers, such as distance from cardiac rehabilitation facilities, inconvenient scheduling, and transportation difficulties. These barriers were similar in Europe and the USA (Jones et al., 2007; Ruano-Ravina et al., 2016).

Despite extensive research in the field of adherence, most previous studies focused on identifying discrete factors that correlate with poor adherence such as age, socioeconomic and cultural attributes, health beliefs, the role of the family, and impact of health care providers. However, there is still a gap in understanding why adherence is poor internationally. Few studies have tried to gain a more holistic approach on motivational aspects from the point of view of patients who experienced a heart attack event.

1.3.1. Theoretical framework

The phenomenon of adherence, as defined by the World Health Organization, is related to people's health behaviors (Sabaté et al., 2003). The reasons people behave in one way or another reflects their beliefs and the way they feel and think. Motivational theories provide conceptual underpinnings of this complex phenomenon. The self-determination theory is a motivational theory that addresses the reasons or goals promoting a behavior. There are two different types of motivation: intrinsic and extrinsic. Intrinsic motivation is "doing something because it is inherently interesting or enjoyable" and extrinsic motivation is "doing something because it leads to a separable outcome" (Ryan and Deci, 2000, p. 55).

Intrinsic motivation can be enhanced when people experience feelings of self-competence and autonomy. Whereas extrinsic motivation is characterized by feelings of being pressured or controlled. However, in general, some adult behaviors are not driven by intrinsic motivations. Social rules and demands often require taking responsibility for actions and tasks that are not necessarily rewarding in terms of interest or pleasure. According to the self-determination theory, processes of internalizing and integrating extrinsic motivations can transform them into intrinsic motivations. These processes are enhanced by adopting external values and regulations, and incorporating them as part of a sense of self (Ryan and Deci, 2000).

Another theory that contributes to a better understanding of the underlying reasoning of human functioning is the self-efficacy theory. Self-efficacy is defined by Bandura (2010) as peoples' beliefs about their competencies to perform during events that affect their lives. A strong sense of self-efficacy enhances people's functioning (i.e., how they feel, think and behave) and their personal well-being. People with strong self-efficacy approach difficult tasks as challenges to be mastered, rather than threats to be avoided. Lack of motivation can result from a personal perception that the cause is not valued; lack of self-efficacy to carry out a behavior; or disbelief that the action will lead to the expected consequences. Competence, autonomy, and relatedness were found to increase intrinsic motivation and support the internalization and integration of extrinsic motivation (Bandura, 2010, 2001; Ryan and Deci, 2000).

The self-determination theory and self-efficacy theory serve as an organizing theoretical framework to better understand the complexity of the phenomenon of adherence. Health care consumers can benefit from health care professionals who increase their motivation for adherence, strengthen their self-efficacy and respect their autonomy. In the context of post MI, empirical studies support this theory, indicating that poor adherence is related to a lack of self-efficacy and motivation. Non-adherence among people post MI was found to be characteristic of people who do not believe efforts to change their lifestyle would result in better health, or did not feel competent to carry out the required changes (Ruano-Ravina et al., 2016). Health care providers should have expertise about human motivation in addition to their clinical expertise, in order to foster among their patients a healthy lifestyle and adherence to medical recommendations.

The aim of this study is to gain deeper insights into perceptions and interpretations that underlie health-related adherence behaviors, from the perspectives of people who have experienced heart attack. The focus of this study is to identify factors that facilitate or inhibit adherence to therapies and healthy lifestyle.

2. Method

2.1. Design

This study used a phenomenological inductive approach and the content analysis method to gain understanding of the adherence phenomenon from the perspectives of people who had experienced MI (Graneheim et al., 2017).

2.2. Participants

A purposive sample of 22 participants post MI were recruited from a hospital cardiac rehabilitation unit and from two different communities in Northern Israel (Table 1). The socio-demographic and cultural characteristics of the participants reflect Israel's population who experienced MI in the past. The participants were chosen from different cultures to obtain a diversity of experiences from different perspectives. The socioeconomic status of the eight Arab respondents was lower, and their level of academic education higher (3/8 Arab participants held bachelor's degrees compared to 3/14 Jewish participants). The majority of Arabs lived in large cities and only two in villages, while eight Jews also lived in cities and six in a kibbutz (i.e., a collective community in Israel traditionally based on agriculture, and today includes industry and high-tech).

2.3. Data collection

A semi-structured in-depth interview guide was developed based on scientific literature, expert peer review by two cardiologist physicians, two cardiology nurses, and three qualitative researchers. The interview guide included a set of 44 predetermined, open-ended questions including prompts, in a way that encouraged participants to convey their viewpoints. In addition, other questions emerged from the dialog. The guide was organized around seven topics: demographics; initial experiences around

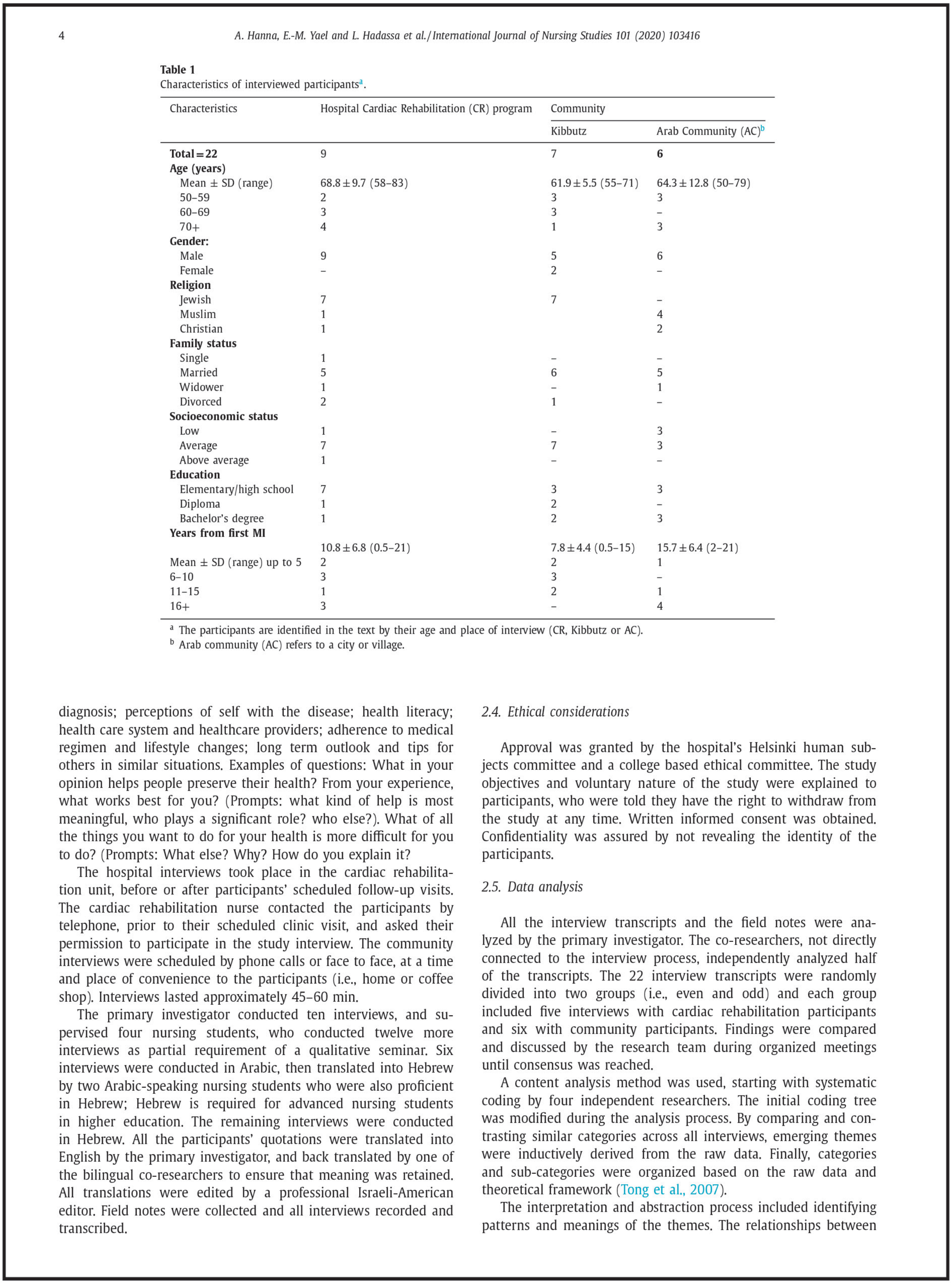

Table 1
Characteristics of interviewed participants[a].

Characteristics	Hospital Cardiac Rehabilitation (CR) program	Community	
		Kibbutz	Arab Community (AC)[b]
Total = 22	9	7	**6**
Age (years)			
Mean ± SD (range)	68.8 ± 9.7 (58–83)	61.9 ± 5.5 (55–71)	64.3 ± 12.8 (50–79)
50–59	2	3	3
60–69	3	3	–
70+	4	1	3
Gender:			
Male	9	5	6
Female	–	2	–
Religion			
Jewish	7	7	–
Muslim	1		4
Christian	1		2
Family status			
Single	1	–	–
Married	5	6	5
Widower	1	–	1
Divorced	2	1	–
Socioeconomic status			
Low	1	–	3
Average	7	7	3
Above average	1	–	–
Education			
Elementary/high school	7	3	3
Diploma	1	2	–
Bachelor's degree	1	2	3
Years from first MI			
	10.8 ± 6.8 (0.5–21)	7.8 ± 4.4 (0.5–15)	15.7 ± 6.4 (2–21)
Mean ± SD (range) up to 5	2	2	1
6–10	3	3	–
11–15	1	2	1
16+	3	–	4

[a] The participants are identified in the text by their age and place of interview (CR, Kibbutz or AC).
[b] Arab community (AC) refers to a city or village.

diagnosis; perceptions of self with the disease; health literacy; health care system and healthcare providers; adherence to medical regimen and lifestyle changes; long term outlook and tips for others in similar situations. Examples of questions: What in your opinion helps people preserve their health? From your experience, what works best for you? (Prompts: what kind of help is most meaningful, who plays a significant role? who else?). What of all the things you want to do for your health is more difficult for you to do? (Prompts: What else? Why? How do you explain it?

The hospital interviews took place in the cardiac rehabilitation unit, before or after participants' scheduled follow-up visits. The cardiac rehabilitation nurse contacted the participants by telephone, prior to their scheduled clinic visit, and asked their permission to participate in the study interview. The community interviews were scheduled by phone calls or face to face, at a time and place of convenience to the participants (i.e., home or coffee shop). Interviews lasted approximately 45–60 min.

The primary investigator conducted ten interviews, and supervised four nursing students, who conducted twelve more interviews as partial requirement of a qualitative seminar. Six interviews were conducted in Arabic, then translated into Hebrew by two Arabic-speaking nursing students who were also proficient in Hebrew; Hebrew is required for advanced nursing students in higher education. The remaining interviews were conducted in Hebrew. All the participants' quotations were translated into English by the primary investigator, and back translated by one of the bilingual co-researchers to ensure that meaning was retained. All translations were edited by a professional Israeli-American editor. Field notes were collected and all interviews recorded and transcribed.

2.4. Ethical considerations

Approval was granted by the hospital's Helsinki human subjects committee and a college based ethical committee. The study objectives and voluntary nature of the study were explained to participants, who were told they have the right to withdraw from the study at any time. Written informed consent was obtained. Confidentiality was assured by not revealing the identity of the participants.

2.5. Data analysis

All the interview transcripts and the field notes were analyzed by the primary investigator. The co-researchers, not directly connected to the interview process, independently analyzed half of the transcripts. The 22 interview transcripts were randomly divided into two groups (i.e., even and odd) and each group included five interviews with cardiac rehabilitation participants and six with community participants. Findings were compared and discussed by the research team during organized meetings until consensus was reached.

A content analysis method was used, starting with systematic coding by four independent researchers. The initial coding tree was modified during the analysis process. By comparing and contrasting similar categories across all interviews, emerging themes were inductively derived from the raw data. Finally, categories and sub-categories were organized based on the raw data and theoretical framework (Tong et al., 2007).

The interpretation and abstraction process included identifying patterns and meanings of the themes. The relationships between

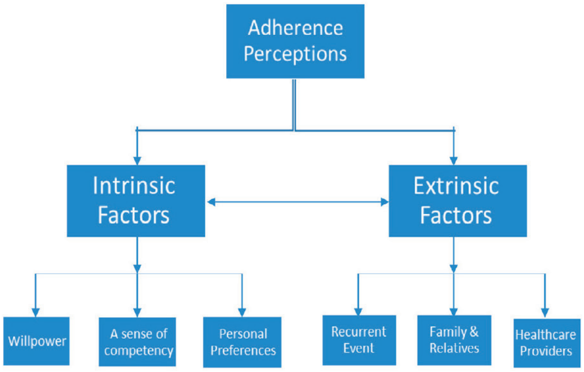

Fig. 1. Adherence to medical recommendations and healthy lifestyle after myocardial infarction: schematic diagram of the study's central category, main categories, sub-categories and the relationships among them.

the core category, main categories, and sub-categories were identified and described. Theoretical saturation was achieved when no new insights were identified from the data. Saturation was reached after eight interviews with cardiac rehabilitation participants and ten interviews with community participants. Four more interviews (two in each group) were conducted to ensure saturation. Finally, the findings were discussed and compared to existing literature (Graneheim et al., 2017).

2.6. Trustworthiness

Criteria of credibility, transferability, dependability, and confirmability were used to establish study trustworthiness (Guba and Lincoln, 1989). Credibility was achieved by in-depth interviews with participants followed by peer debriefing. The primary investigator performed coding, categorization, and analysis of all the data.

Dependability was reached by process audit, i.e., documentation of every step in the analysis process was maintained for evaluation by peer researchers. Confirmability was established by providing a description and rationale for the decisions made based on the findings, helping to ensure they accurately portrayed participants' responses. Transferability was established by extensive descriptions collected through in-depth interviews. The descriptions provide the basis for outside reviewers to judge transferability (Guba and Lincoln, 1989).

3. Findings

In accordance with the study aim, the central focus was the experience of adherence to medical recommendations and healthy lifestyle from the perspective of patients who underwent MI. The abstraction process generated two main categories and six sub-categories embedded in the self-determination theory framework. Fig. 1 demonstrates the formulation of concepts and the relationships among them. In order to understand what motivates people to adhere, the participants were asked to share their experiences of facilitators and barriers to adherence.

3.1. Adherence facilitators and barriers

3.1.1. Intrinsic factors

It is reasonable to assume that people recovering from a heart attack will be highly motivated to maintain good health and prevent recurrence of another heart event. The analysis revealed three themes related to intrinsic motivation: willpower, competency, and individual preferences.

3.1.2. Willpower

A theme that was repeatedly articulated by the participants dealt with self-determination. Participants expressed the need for free will in order to be motivated to incorporate modifications in their lifestyle.

> 67 years (Cardiac rehabilitation) "It's all about will power, you shouldn't panic, it's will power, thinking rationally. I understood that if I will not take care, I will suffer more. I must do something about it. A person must come to the conclusion by himself. Pushing or yelling wouldn't help."

> 60 years (Cardiac rehabilitation) "I have learned from my experience that everything has a price tag and you will have to pay it in at one point in life. If you don't do what you should do, finally you will pay. If you will not watch your weight, or keep on smoking, something will happen to you. A person must be responsible for his life, to take himself in his own hands."

The participants realized that the most important motivator was their choice to take responsibility for the consequences of their health behaviors. They emphasized that no one else could decide for them.

3.1.3. Self-competency

To be aware of the need to adhere and be determined to act in this direction is insufficient for adherence. A theme raised by the participants was related to feelings of self-competency.

> 67 years (Cardiac rehabilitation) "I know what I should eat. If it is not good for me, I can only taste one and not five or six. …If I was able to stop smoking after 40 years three cigarette packages a day, in one second, why shouldn't I be able to stop everything? It's all here (pointed with his finger on his forehead)."

> 58 years (Cardiac rehabilitation) "This time the doctor told me if I want to live, I must quit smoking cigarettes. I don't want to lie to myself. I can't stop all at once. I will not give my body a punch. I don't feel good about it. I feel that something is missing in my life."

Almost all participants described their difficulties in changing habits. Internalization of the risks of non-adherence and having the willpower to change is very important but not sufficient for action. A sense of competency is needed to turn awareness and willingness into practice.

3.1.4. Personal preferences

All participants shared their efforts to adhere, however, difficulties maintaining certain activities varied and depended on individual preferences.

> 83 years (Cardiac rehabilitation) "There are things that I can follow and are not tough for me and there are things that are too tough. … I was told to keep a low salt diet but I do not succeed in doing it. Later on, at night I say to myself that I should behave".

> 60 years (Cardiac rehabilitation) "There are ups and downs in life, I succeeded to quit smoking, trying to stick to a diet, it is difficult with snacks like nuts and seeds, you know… During the last three years I didn't do much walking, gained weight".

Participants found it most difficult to adhere to recommendations that they disliked (e.g., regular exercise activities), or quit enjoyable activities (e.g., smoking, eating habits). They gave many explanations why it was impossible for them to maintain certain habits and activities. Participants that were engaged in some healthy lifestyle habits before the MI found it easier to maintain those activities.

> 78 years (Cardiac rehabilitation) "I live by the sea, all the years I used to swim and I kept swimming after the MI, until today. I do sports activities: walking, swimming, sauna and Jacuzzi. I don't know if it helps, it feels good, I love it!"

According to the participants' experiences, adherence can be enhanced when the individuals decide for themselves to adopt behaviors out of their free will; when they feel competent and challenged to carry out those behaviors; and when engaging in healthy behaviors means to do something they prefer as opposed to being pushed to do things they dislike.

3.2. Extrinsic factors

Three extrinsic factors were identified that play a role as facilitators or barriers to adherence: the threat of a recurrent MI event; family and significant others; and health care providers.

3.2.1. The threat of a recurrent MI

All participants remembered their heart attack very vividly as a critical life-threatening event. Most described feelings of pain they had never experienced and some as intolerable pain. The MI became a turning point that propelled the participants into lifestyle changes immediately following the attack. However, the effect of the event diminished over time and people gradually returned to pre-event habits. Interestingly, the impact of a recurrent MI was described as being of a greater magnitude on their everyday behaviors.

> 58 years (Cardiac rehabilitation) "In the early years after the first attack, let's say two or three years, I kept doing what I was told, then I started eating everything. I did not care what. Life goes on. Shawarma, falafel, all these things. Apparently, it did not do me any good these years. But as soon as I got the other one (nine years later), I got off all this stuff, I threw everything away…. The doctor told me if I want to live longer, I should stop smoking. I have to do these things. I believe this is true. It's up to me."

> 65 years (Kibbutz) "In the first two or three months, maybe one year at the most, I was careful or tried to be careful with what I ate. At first, I went to the family doctor every month, and then the spaces between visits got longer. Listen! I'd do one follow up with a cardiologist each year then I forget about that too."

> 67 years (Kibbutz) "The last attack was so strong that I told myself I'd rather die. Everything would change now. Anything that was wrong would turn out to be all right. If it's cigarettes, if it's a concern for my body, everything… Now my health is first. You see, now the thought that if something happens to me, I will not be here… It should be avoided. I must take care of myself. I will not be here. I'll drag myself as much as possible. Seeing my grandchildren grow up, that's my goal. I had this thought even after the first attack, but you disregard. This time it will not happen."

It appears that the first MI was a warning sign that motivated people to look into their everyday lifestyle behaviors. They realized there are factors under their control that can prevent the next attack and save their life. Over time, adherence declined and participants returned to familiar pre-MI habits, with the hope that it would never recur. A second or recurrent attack made them realize that there was a price for their health conduct. At that point, they felt more decisive to make necessary changes in their lives.

3.2.2. Family and significant others

Family members, mainly spouses, were perceived as a major source for instrumental and psychological support.

> 58 years (Cardiac rehabilitation) "After my first attack I was with my wife, I had family support during the first few years. Everything went well, I stuck to everything, healthy diet, walks on the seashore, she was more into it; I got help and support. Today I live by myself and prepare my own meals, nobody looks after me. I am trying to do what I was told…that's how it is. I think that if I was with a wife it would be easier."

> 56 years (Kibbutz) "If I didn't have such strong support and a network to lean on, I do not know where I would be today. I think because of my family and all the people around, I'm fine."

> 78 years (Arab community) "What helped me is my wife. She asks me, for example, about the medications, whether I took from this box and that. She always pays attention to my food and helped me to quit smoking. I think that family support is very important. You're under pressure and you have to remember a lot, and you get confused, when someone is on your side that helps you, that's good."

Participants who live within a supportive family setting and have an organized agenda found it easier to adhere. The structured family framework helped to maintain daily routine activities, including medical regimens and lifestyle habits. Family members, mainly spouses, provided useful adherence reminders and instrumental help. Feeling that people genuinely care about and support you were perceived as critical for adherence.

While the majority of participants valued family's instrumental and emotional support, some participants felt uncomfortable and offended by others' attitudes regarding their adherence.

> 58 years (Cardiac rehabilitation) "I don't like people telling me what to do. I know what is best for me and what not. I am not a young child. I know exactly what I should do."

> 65 years (Kibbutz) "My wife's family annoyed me somewhat; they had this attitude that I had to be looked after and helped. It's not my character, I mean, no way. In my family its different, we don't look for support and help."

> 59 years (Kibbutz) "Only my wife bothers me, trying to buy healthy food. I'm still buying what I want."

Several participants expressed their resentment being patronized or infantilized by others. They opposed stereotypic comments with no caring intentions. They not only perceived these as not

beneficial, but also sometimes described them as annoying and a motivator for contrary reactions. It appears that a crucial factor for adherence is an attitude of caring that respects the participants' values and preferences.

3.2.3. Health care providers

Health care providers were perceived as another source of external support. Participants were asked what kind of medical follow up and cardiac rehabilitation programs they attend and how it affects their adherence. All participants (i.e., Cardiac rehabilitation and community participants) reported lack of regular planned long-term follow-ups with their family physician or other health professionals (e.g., cardiologist, physical therapist, or dietitian). The community participants reported poor participation in cardiac rehabilitation programs. The initiation for a clinic visit came from the patients, mostly for administrative assistance (e.g., prescriptions, lab tests, referrals), or a health problem. Participants expressed good rapport with their family physician, however, couldn't recall planned follow-ups or regular lifestyle education. Being asked by professionals about adherence to medical recommendations or lifestyle habits was exceptional.

> 74 years (Arab community) "I have a good relationship with my family doctor, I go to him every few months. He asks me how I fee. He checks my blood pressure and tells me to do blood tests. Only if I complain about chest pain, he sends me to do E.C.G. He does not refer me to a cardiologist."

Follow-ups by a cardiologist or a cardiac rehabilitation program is part of a hospitals' discharge recommendations for patients after MI. Most participants interviewed in a community setting provided a variety of explanations and excuses for poor participation, such as: lack of time, distance, felt no need to participate, do not think it is interesting or helpful, and feeling they know best what is good for them.

However, the experience of the group of nine participants interviewed during a hospital-based cardiac rehabilitation visit was different. All of them attended the biannual program voluntarily over many years, since their hospital discharge. Those who ceased the follow up for a period of time experienced deterioration in their lifestyle, and felt the need to return back to the program.

> 83 years (Cardiac rehabilitation) "After I was discharged from the hospital the first time (18 years ago), I continued to come every six months to the cardiac rehabilitation in the hospital. I do not visit the family doctor regularly unless I need something. … For a period of two or three years, I was followed by a cardiologist and was not satisfied. After my wife passed away, I went back to the cardiac rehabilitation in the hospital and since then I have been continuing here twice a year."

> 70 years (Cardiac rehabilitation) "I come here to the nurse every six month since 2004 (14 years). I come on my own initiative, no one tells me. I do every test they say. Stress test, blood test, whatever they decide. The family doctor does not see me. I went to a visit maybe once or twice over the years. I enjoy coming here to the nurse and doctor. I feel their support. … I'm always encouraged when I come here. …It's important for me to get this feedback. That's why I make sure to come."

> 60 years (Cardiac rehabilitation) "The framework here (hospital cardiac rehabilitation) held me. But I stopped coming here for two years. … I reduced my walking the past three years, I gained weight, and I did not take care with food. I decided to return to the framework here. Before I come to follow up, I'm putting myself into a regimen so that I will get there in shape and without problems."

The participants described their experience with the cardiac rehabilitation at the hospital as rewarding in a variety of aspects: a source of reinforcements from experts, an organized structure that helps in maintaining adherence, personal caring relationships with the same familiar team; continuity of long-term care, enjoyable interaction, and receiving professional monitoring, treatment, and guidance. Despite the fact that participation in a hospital-based cardiac rehabilitation program meant extra out of pocket money and long-distance travel, compared to community-based cardiac rehabilitation, the participants emphasized the benefits as worth the investment. They emphasized the benefits, as opposed to non-attending participants who looked for excuses not to participate.

In summary, personal and professional environments such as family, relatives and health care services may have an important impact on adherence or non-adherence.

4. Discussion

The findings of this study demonstrate the complexity of the adherence phenomenon and shed some light on the underlying motivators to health-related behaviors. Three intrinsic adherence factors were identified: willpower, sense of competency, and personal preferences. The underlying meaning of the interrelationships was that willpower by itself is insufficient for a person to adhere to a change in life; a sense of competency is required to enable carrying out a change that fits the person's beliefs and preferences. Similarly, the extrinsic factors were interrelated. A person experiencing a stressful event, such as MI, can benefit from support by relatives and health care professionals. Moreover, external and internal attributes are also interrelated, whereby external events and environment can enhance or impede internal attributes and vice versa.

Willpower was identified by the participants as a crucial motivator for behavioral change and supports the importance of inner determination as a major adherence facilitator. This finding is in congruence with the self-determination theory (Ryan and Deci, 2000), and emphasizes the importance of the autonomy of people to choose their own way of life (Bergman and Berterö, 2003). This kind of determination was based primarily on the participants' ability to internalize the consequences of their behavior. Although most participants were knowledgeable and aware of the costs of non-adherence, they still found it difficult to integrate this knowledge into action in their everyday lifestyle.

People with chronic health conditions are often expected to give up personal preferred habits and replace them with less enjoyable, or even unpleasant medical regimens. According to the self-determination theory, the actions of people who are intrinsically motivated depend on whether it gives them pleasure or interest. This explains to some extent why even those who internalize the implications of non-adherence and have a sense of volition, found it difficult to adhere. In light of this understanding, a cardinal question is what differentiates between people who adhere and those who do not?

Findings of the current study suggest that beyond inner-willpower, a sense of self-efficacy (Bandura, 2001) or self-competency along with the ability to tailor behavioral changes according to personal beliefs and preferences, can turn intentions into practice. Participants with high adherence were those who succeeded in integrating all three components. In other words, they had strong will power to live healthy life and felt competent to integrate preferable changes in everyday lifestyle, even though they were not necessarily their most favored choices.

As much as intrinsic motivators play a crucial role in adherence, internalization of extrinsic motivators can strengthen the inner sense of self determination and competency. The threat of a recurrent heart attack, family members, and healthcare

professionals were found to be external factors with the potential to affect adherence. Family support, especially spousal support, and structured daily life were identified as factors that encouraged adherence. This finding is consistent with the literature, indicating that people characterized by non-adherence often lived alone, felt socially isolated, or felt controlled and overprotected by their families (Dunbar et al., 2008; Fernandez et al., 2015; Roebuck et al., 2001). Caring relations provided with respect to a person's values, preferences and autonomy supported their basic needs for competence, control, and relatedness (Ryan and Deci, 2000).

All participants (i.e., Cardiac rehabilitation and community participants) reported lack of regular planned long-term follow-up with their family physician or other health professionals (e.g., cardiologist, physical therapist, or dietitian). The community participants reported poor participation in cardiac rehabilitation programs. Those who attended hospital-based cardiac rehabilitation visits regularly emphasized the benefits of their program: routine monitoring, evaluation of health status, feedback and guidance from experts, continuity of care over years, and a personal patient-centered approach. They further emphasized that it filled their needs for reassurance, confidence and trust that was worth the effort and costs required to attend a hospital-based program.

In the current study there were some socioeconomic gaps between Jewish and Arab participants, however, this did not associate with differences in health literacy and adherence perceptions. A possible explanation might be the greater influence of similar social environments and level of education, compared to differences in cultural or religious attributes.

None of the emerged themes was identified as a sole solution to the poor adherence problem. The understanding that the phenomenon of adherence is a complex holistic integration of internal and external motivators and the interrelationships among them could advance theoretical understanding and lead to important practical implications.

4.1. Limitations

Most of the participants in the current study represent normative adherence behaviors. More interviews with non-adherent people would be beneficial to gain a better understanding of non-adherence perspectives. Although the prevalence of MI is higher among men and it was convenient to recruit them, more women should be involved in this research. The interviews were conducted in Hebrew or Arabic and translated into English, which may have misrepresented the laymen language. Transferability should take into consideration socio-cultural differences.

5. Conclusion

The motivational theory was a useful framework to organize the interview data and gain insights to the underlying motivators of the phenomenon of adherence to health-related behaviors. Primary and secondary long-term cardiac care interventions are recommended to incorporate tailored behavior change strategies that would enhance adherence to therapies and healthy lifestyle. Health care practitioners should establish mutually agreed upon plans of care, in cooperation with patients, rather than dictate medical instructions for the patient. In addition, specific objectives should be established with regular planned follow up. Future research should evaluate the effectiveness of interventions designed to strengthen motivation and enhance adherence.

Conflict of interest

None declared.

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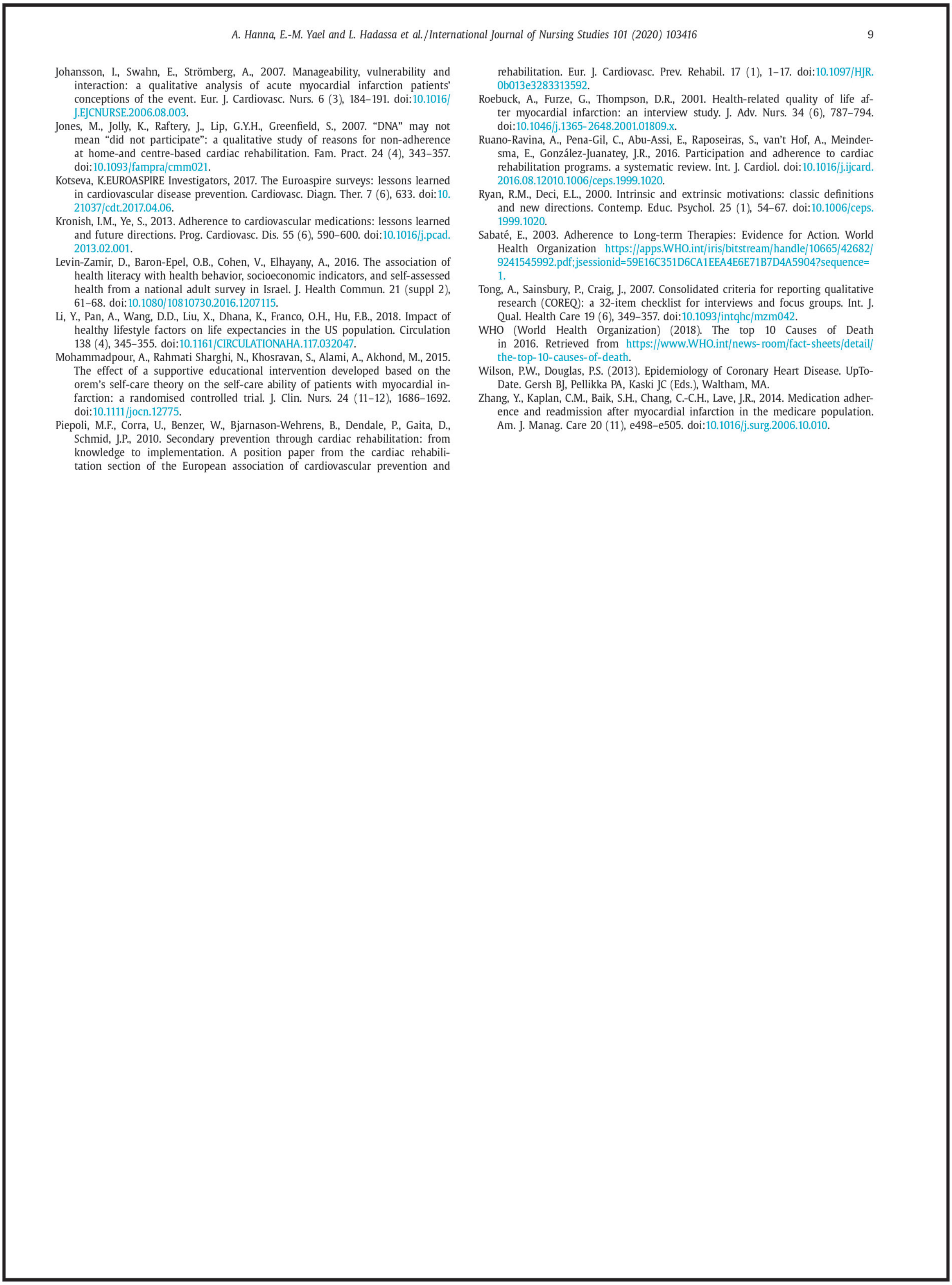

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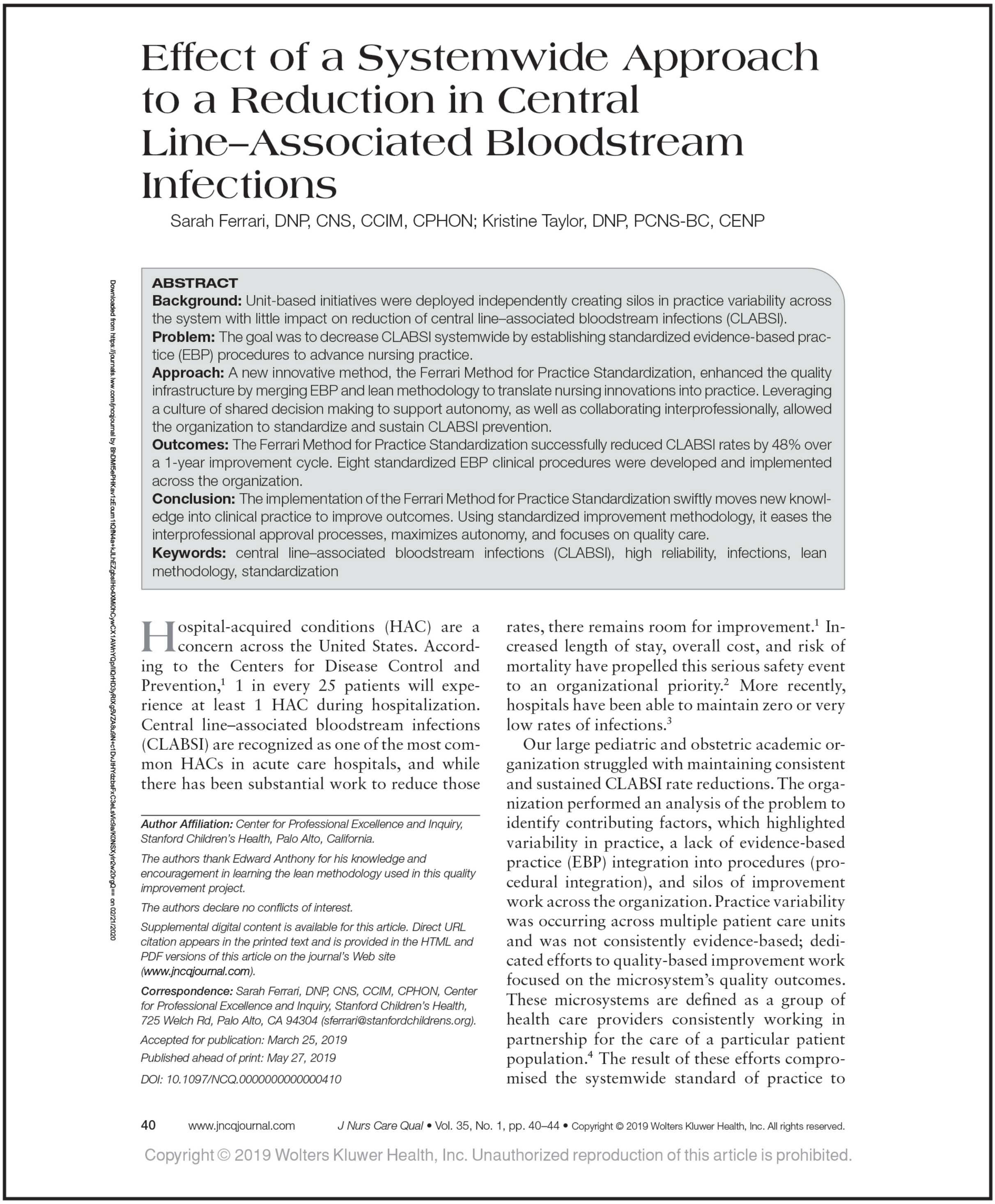

Effect of a Systemwide Approach to a Reduction in Central Line–Associated Bloodstream Infections

Sarah Ferrari, DNP, CNS, CCIM, CPHON; Kristine Taylor, DNP, PCNS-BC, CENP

ABSTRACT
Background: Unit-based initiatives were deployed independently creating silos in practice variability across the system with little impact on reduction of central line–associated bloodstream infections (CLABSI).
Problem: The goal was to decrease CLABSI systemwide by establishing standardized evidence-based practice (EBP) procedures to advance nursing practice.
Approach: A new innovative method, the Ferrari Method for Practice Standardization, enhanced the quality infrastructure by merging EBP and lean methodology to translate nursing innovations into practice. Leveraging a culture of shared decision making to support autonomy, as well as collaborating interprofessionally, allowed the organization to standardize and sustain CLABSI prevention.
Outcomes: The Ferrari Method for Practice Standardization successfully reduced CLABSI rates by 48% over a 1-year improvement cycle. Eight standardized EBP clinical procedures were developed and implemented across the organization.
Conclusion: The implementation of the Ferrari Method for Practice Standardization swiftly moves new knowledge into clinical practice to improve outcomes. Using standardized improvement methodology, it eases the interprofessional approval processes, maximizes autonomy, and focuses on quality care.
Keywords: central line–associated bloodstream infections (CLABSI), high reliability, infections, lean methodology, standardization

Hospital-acquired conditions (HAC) are a concern across the United States. According to the Centers for Disease Control and Prevention,[1] 1 in every 25 patients will experience at least 1 HAC during hospitalization. Central line–associated bloodstream infections (CLABSI) are recognized as one of the most common HACs in acute care hospitals, and while there has been substantial work to reduce those rates, there remains room for improvement.[1] Increased length of stay, overall cost, and risk of mortality have propelled this serious safety event to an organizational priority.[2] More recently, hospitals have been able to maintain zero or very low rates of infections.[3]

Our large pediatric and obstetric academic organization struggled with maintaining consistent and sustained CLABSI rate reductions. The organization performed an analysis of the problem to identify contributing factors, which highlighted variability in practice, a lack of evidence-based practice (EBP) integration into procedures (procedural integration), and silos of improvement work across the organization. Practice variability was occurring across multiple patient care units and was not consistently evidence-based; dedicated efforts to quality-based improvement work focused on the microsystem's quality outcomes. These microsystems are defined as a group of health care providers consistently working in partnership for the care of a particular patient population.[4] The result of these efforts compromised the systemwide standard of practice to

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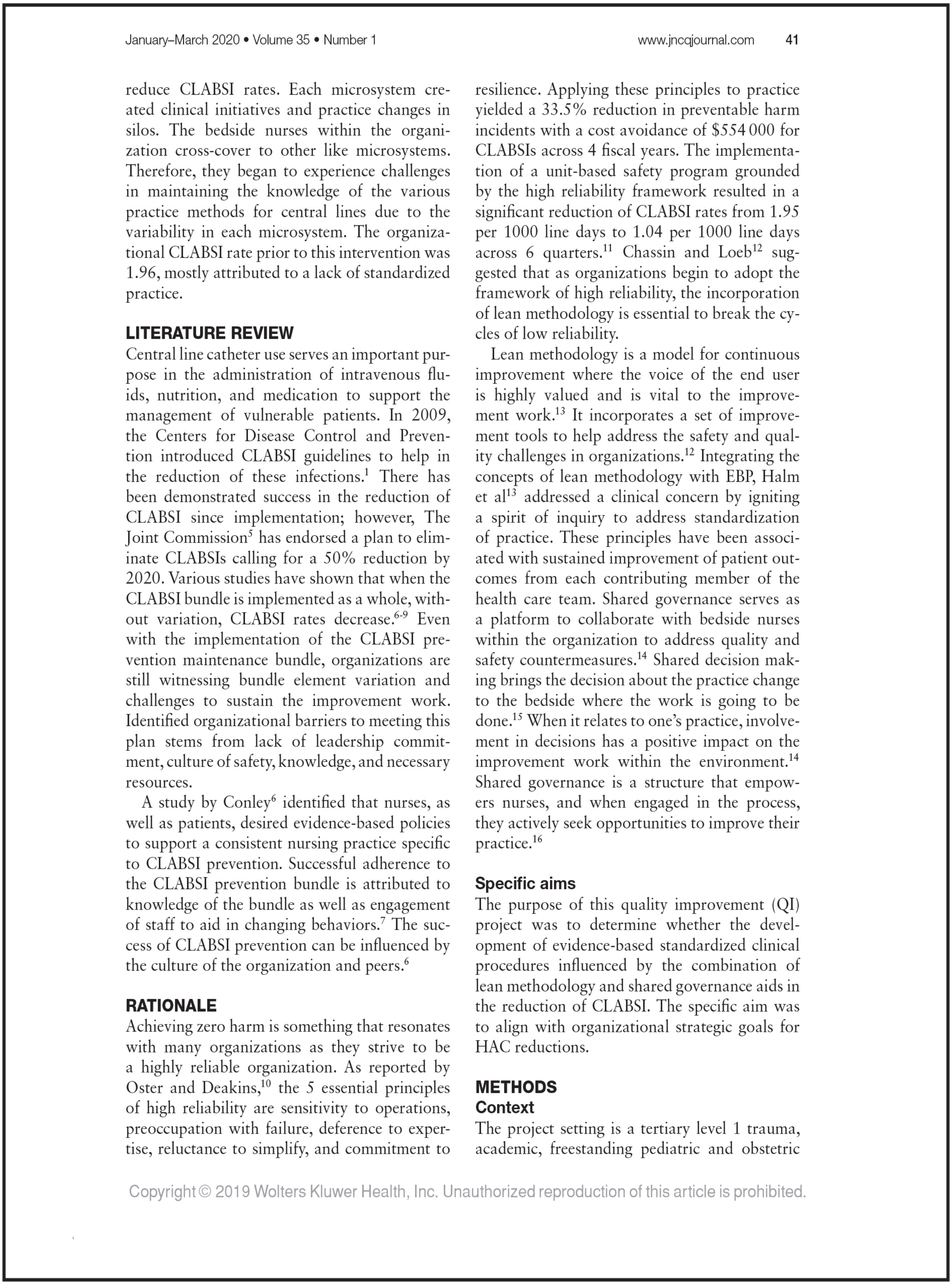


reduce CLABSI rates. Each microsystem created clinical initiatives and practice changes in silos. The bedside nurses within the organization cross-cover to other like microsystems. Therefore, they began to experience challenges in maintaining the knowledge of the various practice methods for central lines due to the variability in each microsystem. The organizational CLABSI rate prior to this intervention was 1.96, mostly attributed to a lack of standardized practice.

LITERATURE REVIEW

Central line catheter use serves an important purpose in the administration of intravenous fluids, nutrition, and medication to support the management of vulnerable patients. In 2009, the Centers for Disease Control and Prevention introduced CLABSI guidelines to help in the reduction of these infections.[1] There has been demonstrated success in the reduction of CLABSI since implementation; however, The Joint Commission[5] has endorsed a plan to eliminate CLABSIs calling for a 50% reduction by 2020. Various studies have shown that when the CLABSI bundle is implemented as a whole, without variation, CLABSI rates decrease.[6-9] Even with the implementation of the CLABSI prevention maintenance bundle, organizations are still witnessing bundle element variation and challenges to sustain the improvement work. Identified organizational barriers to meeting this plan stems from lack of leadership commitment, culture of safety, knowledge, and necessary resources.

A study by Conley[6] identified that nurses, as well as patients, desired evidence-based policies to support a consistent nursing practice specific to CLABSI prevention. Successful adherence to the CLABSI prevention bundle is attributed to knowledge of the bundle as well as engagement of staff to aid in changing behaviors.[7] The success of CLABSI prevention can be influenced by the culture of the organization and peers.[6]

RATIONALE

Achieving zero harm is something that resonates with many organizations as they strive to be a highly reliable organization. As reported by Oster and Deakins,[10] the 5 essential principles of high reliability are sensitivity to operations, preoccupation with failure, deference to expertise, reluctance to simplify, and commitment to resilience. Applying these principles to practice yielded a 33.5% reduction in preventable harm incidents with a cost avoidance of $554 000 for CLABSIs across 4 fiscal years. The implementation of a unit-based safety program grounded by the high reliability framework resulted in a significant reduction of CLABSI rates from 1.95 per 1000 line days to 1.04 per 1000 line days across 6 quarters.[11] Chassin and Loeb[12] suggested that as organizations begin to adopt the framework of high reliability, the incorporation of lean methodology is essential to break the cycles of low reliability.

Lean methodology is a model for continuous improvement where the voice of the end user is highly valued and is vital to the improvement work.[13] It incorporates a set of improvement tools to help address the safety and quality challenges in organizations.[12] Integrating the concepts of lean methodology with EBP, Halm et al[13] addressed a clinical concern by igniting a spirit of inquiry to address standardization of practice. These principles have been associated with sustained improvement of patient outcomes from each contributing member of the health care team. Shared governance serves as a platform to collaborate with bedside nurses within the organization to address quality and safety countermeasures.[14] Shared decision making brings the decision about the practice change to the bedside where the work is going to be done.[15] When it relates to one's practice, involvement in decisions has a positive impact on the improvement work within the environment.[14] Shared governance is a structure that empowers nurses, and when engaged in the process, they actively seek opportunities to improve their practice.[16]

Specific aims

The purpose of this quality improvement (QI) project was to determine whether the development of evidence-based standardized clinical procedures influenced by the combination of lean methodology and shared governance aids in the reduction of CLABSI. The specific aim was to align with organizational strategic goals for HAC reductions.

METHODS

Context

The project setting is a tertiary level 1 trauma, academic, freestanding pediatric and obstetric

hospital with 361 patient beds located in California. This organization has a diverse patient population with more than 150 medical specialty services in 6 different clinical groupings or what the organization calls centers of excellence. Inclusion criteria for this QI project were all inpatient units that used central lines from February 2017 to November 2018. The institutional review board at Stanford University deemed this project as QI.

Interventions

Unacceptable CLABSI rates prompted 2 nurses in the Center for Professional Development and Inquiry, experienced in lean methodology and shared governance, to partner with Patient Care Services to implement a new methodology called the Ferrari Method for Practice Standardization (the Ferrari Method). This methodology integrates lean methodology tools with EBP in an effort to streamline and standardize clinical practice. The organization was familiar with each method independently but had never merged these methods together for improvement work. This combination aligned strategic plans, used the shared governance council membership and structure, and incorporated EBP to streamlined approval processes. The Ferrari Method structure involved preplanning activities, work group sessions with the content experts, socialization of recommendations, finalization of the change, and implementation strategies. The team consisted of shared governance bedside nurses from both the inpatient and outpatient areas, members from the Professional Development Council (clinical nurse specialists and nursing professional development specialists), infection prevention and control specialists, a member from the vascular access department, a member from the quality department, providers, a member from supply chain, and the policy program manager as the facilitator. In addition, a lead educator was assigned to assume responsibility for continually assessing the level of education and educational methods throughout the process. Lean methodology served as the basis for the construction of the agenda and charters for each breakout session. These charters served as a tool to guide the team members through the various discussions based on their assigned clinical skill group.

Each workshop consisted of two 4-hour workshops with an overall aim to understand current practice, evaluate the evidence, gain consensus, and construct new standardized clinical house-wide procedures. The first workshop focused on understanding current practice differences across the organization, reviewing the literature, and developing an appraisal table. In between sessions 1 and 2, the team members discussed the ideal best practice proposals with their peers. The second 4-hour workshop focused on revisiting the proposed best practice by weighing the feedback received from peers and constructing the standardized procedures for each identified skill. The educational level was assessed to determine ideal peer-based dissemination and implementation using technology and skill-based education.

Study of interventions

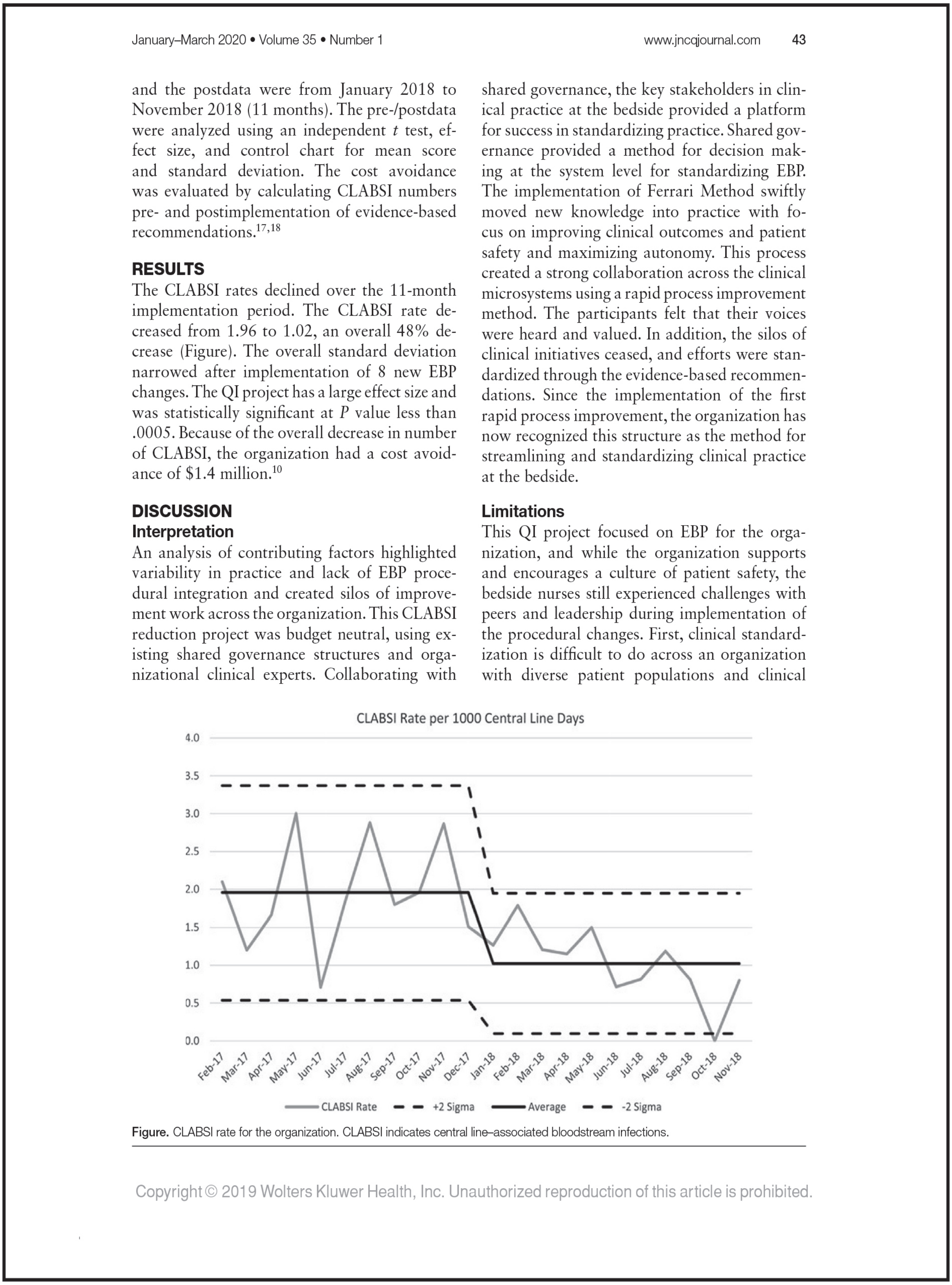
Eight standardized procedures specific to the maintenance of central lines were implemented across the organization over the fiscal year. Over a span of 4 months, organizational consensus was obtained on these 8 evidence-based policies and procedures (see Supplemental Digital Content Table, available at: http://links.lww.com/JNCQ/A590). Once implementation across the organization was complete, the unit's leadership team assessed and gathered feedback from bedside staff with newly implemented procedures and policies. The cyclic evaluation cycles, using the Plan-Do-Study-Act workflow, were deployed 6 months post each new procedure implementation to allow for skill acquisition. To measure the success of the newly implemented standardized procedures, evaluation of CLABSI rates pre- and postimplementation was compared.

Measures

The outcome measure for CLABSI was defined by National Health care Safety Network and reviewed monthly by the infection prevention and control team. The CLABSI rate is calculated by dividing the total number of central line infections per month (numerator) by the total number of central line days (denominator) times 1000 patient days. The cost avoidance calculation is provided by Goudie et al[17] and Goudie et al.[18] The EBP changes were measured by the total number of policy/procedure updates during the implementation time period.

Analysis

The CLABSI rate baseline data were from February 2017 to December 2017 (11 months),



and the postdata were from January 2018 to November 2018 (11 months). The pre-/postdata were analyzed using an independent *t* test, effect size, and control chart for mean score and standard deviation. The cost avoidance was evaluated by calculating CLABSI numbers pre- and postimplementation of evidence-based recommendations.[17,18]

RESULTS

The CLABSI rates declined over the 11-month implementation period. The CLABSI rate decreased from 1.96 to 1.02, an overall 48% decrease (Figure). The overall standard deviation narrowed after implementation of 8 new EBP changes. The QI project has a large effect size and was statistically significant at *P* value less than .0005. Because of the overall decrease in number of CLABSI, the organization had a cost avoidance of $1.4 million.[10]

DISCUSSION

Interpretation

An analysis of contributing factors highlighted variability in practice and lack of EBP procedural integration and created silos of improvement work across the organization. This CLABSI reduction project was budget neutral, using existing shared governance structures and organizational clinical experts. Collaborating with shared governance, the key stakeholders in clinical practice at the bedside provided a platform for success in standardizing practice. Shared governance provided a method for decision making at the system level for standardizing EBP. The implementation of Ferrari Method swiftly moved new knowledge into practice with focus on improving clinical outcomes and patient safety and maximizing autonomy. This process created a strong collaboration across the clinical microsystems using a rapid process improvement method. The participants felt that their voices were heard and valued. In addition, the silos of clinical initiatives ceased, and efforts were standardized through the evidence-based recommendations. Since the implementation of the first rapid process improvement, the organization has now recognized this structure as the method for streamlining and standardizing clinical practice at the bedside.

Limitations

This QI project focused on EBP for the organization, and while the organization supports and encourages a culture of patient safety, the bedside nurses still experienced challenges with peers and leadership during implementation of the procedural changes. First, clinical standardization is difficult to do across an organization with diverse patient populations and clinical

Figure. CLABSI rate for the organization. CLABSI indicates central line–associated bloodstream infections.

needs. This led to the creation of an approved plan for exceptions based on evidence for specific patient populations with various products and/or central line devices. Second, procedural changes were evidence-based, but some patient care units experienced challenges with staff adoption of the change in practice due to disbelief in the evidence. This, therefore, negatively influenced early adopters. Additional education was needed for some areas to better comprehend the evidence. Finally, during the cycles of improvement postimplementation, feedback was provided regarding challenges to obtain the right supplies in a timely fashion. A timed study of the practice changes before and after the change in technique to assess workflow changes or skill acquisition may have helped compliance and understanding of time needed for each practice.

CONCLUSIONS

The specific aim of this project was to decrease CLABSI rates through an organizational focus and standardization of EBP. The creation of Ferrari Method proved to be a valid method for assessing practice, evaluating the evidence, and developing practice standards. Pulling clinical experts from the microsystems established a standard method for the decision making. In conclusion, CLABSI rates decreased after establishing the Ferrari Method for Practice Standardization of organization procedures, supporting high reliability, improving bundle knowledge, and encouraging bedside nurse engagement.

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