La lettura critica dell'articolo scientifico

Il Processo di Ricerca

Turci C et al. L'infermiere oggi. 2013

La struttura (più o meno standard) dell'articolo

- Titolo e autori
- Abstract
- Introduzione
- Metodi
- Risultati
- Discussione
- Limiti
- Conclusioni
- Conflitti d'interesse
- Bibliografia

Titolo e autori

- Il titolo fornisce informazioni sull'importanza dell'articolo rispetto ai propri interessi
- Il titolo dovrebbe contenere i dati essenziali per capire di che cosa si sta parlando
- Non è detto che autori noti o di istituzioni prestigiose pubblichino sempre lavori di qualità o interessanti

BMJ

RESEARCH

Risk of miscarriage with bivalent vaccine against human papillomavirus (HPV) types 16 and 18: pooled analysis of two randomised controlled trials

Conclusion There is no evidence overall for an association between HPV vaccination and risk of miscarriage.

Combined Measurement of the Higgs Boson Mass in pp Collisions at $\sqrt{s} = 7$ and 8 TeV with the ATLAS and CMS Experiments

G. Aad *et al.*[*]

(ATLAS Collaboration)[†]
(CMS Collaboration)[‡]

(Received 25 March 2015; published 14 May 2015)

A measurement of the Higgs boson mass is presented based on the combined data samples of the ATLAS and CMS experiments at the CERN LHC in the $H \to \gamma\gamma$ and $H \to ZZ \to 4\ell$ decay channels. The results are obtained from a simultaneous fit to the reconstructed invariant mass peaks in the two channels and for the two experiments. The measured masses from the individual channels and the two experiments are found to be consistent among themselves. The combined measured mass of the Higgs boson is $m_H = 125.09 \pm 0.21\,(\text{stat}) \pm 0.11\,(\text{syst})$ GeV.

DOI: 10.1103/PhysRevLett.114.191803 PACS numbers: 14.80.Bn, 13.85.Qk

The study of the mechanism of electroweak symmetry breaking is one of the principal goals of the CERN LHC program. In the standard model (SM), this symmetry breaking is achieved through the introduction of a complex doublet scalar field, leading to the prediction of the Higgs boson H [1–6], whose mass m_H is, however, not predicted by the theory. In 2012, the ATLAS and CMS Collaborations at the LHC announced the discovery of a particle with Higgs-boson-li
about 125 GeV [7–9]. The d
on mass peaks observed in t
(denoted $H \to ZZ \to 4\ell$ fo
where one or both of the Z
where ℓ and ℓ' denote an
known, all properties of the
production cross section and
predicted. Increasingly precis
established that all observed
including its spin, parity, a
particles are consistent withi
expected for the SM Higgs
The ATLAS and CMS C
ently measured m_H using the samples of proton-proton collision data collected in 2011 and 2012, commonly referred to as LHC Run 1. The analyzed samples correspond to approximately 5 fb^{-1} of integrated luminosity at $\sqrt{s} = 7$ TeV, and 20 fb^{-1} at $\sqrt{s} = 8$ TeV, for each experiment. Combined results in the context of the separate experiments, as well as those in the individual channels, are presented in Refs. [12,14–16].

This Letter describes a combination of the Run 1 data from the two experiments, leading to improved precision for m_H. Besides its intrinsic importance as a fundamental parameter, improved knowledge of m_H yields more precise predictions for the other Higgs boson properties. Furthermore, the combined mass measurement provides a first step towards combinations of other quantities, such as the couplings. In the SM, m_H is related to the values of

presented in Refs. [12,14–16].

[*]Full author list given at the end of the article.

Published by the American Physical Society under

SM value, which is small compared to the current precision. The effect in the $H \to ZZ \to 4\ell$ channel is expected to be much smaller [21]. The effects of the interference on the mass spectra are neglected in this Letter.

The ATLAS and CMS detectors [22,23] are designed to precisely reconstruct charged leptons, photons, hadronic jets, and the imbalance of momentum transverse to the direction of the beams. The two detectors are based on different technologies requiring different reconstruction and calibration methods. Consequently, they are subject to different sources of systematic uncertainty.

The $H \to \gamma\gamma$ channel is characterized by a narrow resonant signal peak containing several hundred events per experiment above a large falling continuum background. The overall signal-to-background ratio is a few

[*]Full author list given at the end of the article.

5.154 autori!

… 16 pagine …

L’importanza di quell’asterisco

Maternal Nutrition and Body Composition During Breastfeeding: Association with Human Milk Composition

Agnieszka Bzikowska-Jura [1], Aneta Czerwonogrodzka-Senczyna [1], Gabriela Olędzka [2,*], Dorota Szostak-Węgierek [1], Halina Weker [1] and Aleksandra Wesołowska [3]

1 Department of Clinical Dietetics, Faculty of Health Science, Medical University of Warsaw, E Ciolka Str. 27, 01-445 Warsaw, Poland; agnieszka.bzikowska@wum.edu.pl (A.B.-J.); aneta.senczyna@wum.edu.pl (A.C.-S.); dorota.szostak-wegierek@wum.edu.pl (D.S.-W.); halina.weker@wum.edu.pl (H.W.)

2 Department of Medical Biology, Faculty of Health Science, Medical University of Warsaw, Nowogrodzka Str. 73, 02-018 Warsaw, Poland

3 Laboratory of Human Milk and Lactation Research at Regional Human Milk Bank in Holy Family Hospital, Faculty of Health Science, Department of Neonatology, Medical University of Warsaw, Zwirki i Wigury Str. 63A, 02-091 Warsaw, Poland; aleksandra.wesolowska@wum.edu.pl

* Correspondence: gabriela.oledzka@wum.edu.pl; Tel.: +48-22-625-32-23

The «author contribution statement»

A.B., B.C., C.D., D.E., E.F., F.G., and G.H. conceived and planned the experiments. A.B., B.C., C.D. and D.E. carried out the experiments. A.B., F.G. and E.F. planned and carried out the simulations. J.K., K.L., A.B., B.C., D.E., C.D., F.J., and F.G. contributed to sample preparation. A.B., B.C., C.D., D.E., FJ, E.F., F.G. and G.H. contributed to the interpretation of the results. A.B. took the lead in writing the manuscript. All authors provided critical feedback and helped shape the research, analysis and manuscript.

Journal of
Clinical Medicine

MDPI

Article

Impact of Transitory ROSC Events on Neurological Outcome in Patients with Out-of-Hospital Cardiac Arrest

Vittorio Antonaglia [1], Carlo Pegani [1], Giuseppe Davide Caggegi [2], Athina Patsoura [3], Veronica Xu [4], Marco Zambon [2] and Gianfranco Sanson [5,*]

1 Regional Emergency Medical Service System, Azienda Regionale Coordinamento della Salute, 33057 Udine, Italy
2 Emergency Medical Service System, Azienda Sanitaria Universitaria Integrata, 734128 Trieste, Italy
3 Department of Surgery, Dentistry, Paediatrics and Gynaecology, School of Medicine, University of Verona, 837129 Verona, Italy
4 Azienda USL Toscana Sud Est, 54-52100 Arezzo, Italy
5 Department of Medicine, Surgery and Health Sciences, University of Trieste, 9-34100 Piazzale Europa, Italy
* Correspondence: gsanson@units.it; Tel.: +39-040-825-966; Fax: +39-040-828-063

Author Contributions: Conceptualization, V.A. and G.S.; Methodology, V.A. and G.S.; Investigation, G.D.C., A.P., V.X. and M.Z.; Data Curation, C.P.; Data Analysis, G.S.; Writing—Original Draft Preparation, G.S.; Writing—Review & Editing, V.A.; Supervision, V.A. Each author approved the final version of the Manuscript as submitted to the Journal and agreed to be personally accountable for the author's own contributions and for ensuring that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and documented in the literature.

Abstract

- Consente di determinare la rilevanza dell'articolo e di identificare rapidamente i dati salienti
- Può essere strutturato in sottosezioni
- Non permette una valutazione critica dello studio, che può aversi solo leggendo tutto il lavoro

ABSTRACT

Objective To assess whether vaccination against human papillomavirus (HPV) increases the risk of miscarriage.

Design Pooled analysis of two multicentre, phase three masked randomised controlled trials

Setting Multicentre trials in several continents and in Costa Rica.

Participants 26 130 women aged 15-25 at enrolment; 3599 pregnancies eligible for analysis.

Interventions Participants were randomly assigned to receive three doses of bivalent HPV 16/18 VLP vaccine with AS04 adjuvant (n=13 075) or hepatitis A vaccine as control (n=13 055) over six months.

Main outcome measures Miscarriage and other pregnancy outcomes.

Results The estimated rate of miscarriage was 11.5% in pregnancies in women in the HPV arm and 10.2% in the control arm. The one sided P value for the primary analysis was 0.16; thus, overall, there was no significant increase in miscarriage among women assigned to the HPV vaccine arm. In secondary descriptive analyses, miscarriage rates were 14.7% in the HPV vaccine arm and 9.1% in the control arm in pregnancies that began within three months after nearest vaccination.

Conclusion There is no evidence overall for an association between HPV vaccination and risk of miscarriage.

Trial registration Clinical Trials NCT00128661 and NCT00122681.

Introduzione

- Contribuisce a inquadrare la sperimentazione e la sua credibilità sulla base di quanto già noto (background)
- Spiega perché si è deciso di condurre la nuova ricerca
- Indica quali sono le ipotesi che si vogliono valutare nello studio

Quality of Cardiopulmonary Resuscitation During Out-of-Hospital Cardiac Arrest

Lars Wik, MD, PhD
Jo Kramer-Johansen, MD
Helge Myklebust, BEng
Hallstein Sørebø, MD
Leif Svensson, MD
Bob Fellows, MD
Petter Andreas Steen, MD, PhD

Context Cardiopulmonary resuscitation (CPR) guidelines recommend target values for compressions, ventilations, and CPR-free intervals allowed for rhythm analysis and defibrillation. There is little information on adherence to these guidelines during advanced cardiac life support in the field.

Objective To measure the quality of out-of-hospital CPR performed by ambulance personnel, as measured by adherence to CPR guidelines.

Design and Setting Case series of 176 adult patients with out-of-hospital cardiac arrest treated by paramedics and nurse anesthetists in Stockholm, Sweden, London, England, and Akershus, Norway, between March 2002 and October 2003. The defibrillators recorded chest compressions via a sternal pad fitted with an accelerometer and ventilations by changes in thoracic impedance between the defibrillator pads, in addition to standard event and electrocardiographic recordings.

Main Outcome Measure Adherence to international guidelines for CPR.

Results Chest compressions were not given 48% (95% CI, 45%-51%) of the time without spontaneous circulation; this percentage was 38% (95% CI, 36%-41%) when subtracting the time necessary for electrocardiographic analysis and defibrillation. Combining these data with a mean compression rate of 121/min (95% CI, 118-124/min) when compressions were given resulted in a mean compression rate of 64/min (95% CI, 61-67/min). Mean compression depth was 34 mm (95% CI, 33-35 mm), 28% (95% CI, 24%-32%) of the compressions had a depth of 38 mm to 51 mm (guidelines recommendation), and the compression part of the duty cycle was 42% (95% CI, 41%-42%). A mean of 11 (95% CI, 11-12) ventilations were given per minute. Sixty-one patients (35%) had return of spontaneous circulation, and 5 of 6 patients discharged alive from the hospital had normal neurological outcomes.

Conclusions In this study of CPR during out-of-hospital cardiac arrest, chest compressions were not delivered half of the time, and most compressions were too shallow. Electrocardiographic analysis and defibrillation accounted for only small parts of intervals without chest compressions.

JAMA. 2005;293:299-304 www.jama.com

SINCE THE FIRST STANDARDS AND guidelines for cardiopulmonary resuscitation (CPR) were published 30 years ago[1] (with the latest update in 2000[2,3]) health care professionals in and out of the hospital have been trained accordingly around the world. The importance of CPR, defined as chest compressions and ventilation, for survival of cardiac arrest patients has been demonstrated,[4] and there are indications that the quality of CPR performance influences the outcome.[5-7]

When tested on mannequins, CPR quality performed by lay rescuers and health care professionals tends to deteriorate significantly within a few months after training,[8-10] but little is known about the quality of clinical performance on patients. Aufderheide et al[11] recently observed short periods with inappropriately high ventilation rates during advanced cardiac life support (ACLS), and van Alem et al[12] found long pauses in CPR when first responders used automated external defibrillators.

We therefore studied the performance of paramedics and nurse anesthetists during out-of-hospital ACLS by continuously monitoring all chest compressions and ventilations during resuscitation episodes using online defibrillators modified to collect such data.

See also pp 305 and 363, and Patient Page.

METHODS

Patient Inclusion and Recruitment

The study was approved by the regional ethics committees for Akershus, Norway, Stockholm, Sweden, and London, England. Informed consent for inclusion in the study was waived as decided by these committees in accordance with paragraph 26 in the Declaration of Helsinki.[13] The study was a case series involving patients older than

Author Affiliations: National Competence Center for Emergency Medicine (Dr Wik), Institute for Experimental Medical Research (Drs Wik, Kramer-Johansen, and Steen), Division of Prehospital Emergency Medicine (Drs Wik, Sørebø, and Steen), and Division of Surgery (Dr Steen), Ulleval University Hospital, Oslo, Norway; Norwegian Air Ambulance, Department of Research and Education in Acute Medicine, Drøbak, Norway (Dr Kramer-Johansen); Laerdal Medical, Corp, Stavanger, Norway (Mr Myklebust); Sodersjukhuset, Stockholm, Sweden (Dr Svensson); London Ambulance Service NHS Trust, London, England (Dr Fellows).
Financial Disclosure: Mr Myklebust is an employee of Laerdal Medical Corp, which developed the monitor/defibrillator.
Corresponding Author: Lars Wik, MD, PhD, NAKOS, Institute for Experimental Medical Research, Ulleval University Hospital, N-0407 Oslo, Norway.

JAN
Informing Practice and Policy Worldwide through Research and Scholarship

ORIGINAL RESEARCH: EMPIRICAL RESEARCH – QUANTITATIVE

Prevalence of nursing diagnoses as a measure of nursing complexity in a hospital setting

Fabio D'Agostino, Gianfranco Sanson, Antonello Cocchieri, Ercole Vellone, John Welton, Massimo Maurici, Rosaria Alvaro & Maurizio Zega

Why is this research needed?

- Since nursing diagnoses represent the clinical judgement of nurses, they can be a measure of nursing dependency and nursing complexity.
- The nursing diagnoses collected at admission can provide a picture of the nursing needs in the first hours of care and, consequently, the outcomes to achieve and the interventions to perform.
- The initial diagnostic pattern may allow healthcare teams to make a prognosis regarding hospital outcomes, such as mortality and length of stay.

What are the key findings?

- The number and patterns of nursing diagnoses per patient identified on admission describe patients with broadly different nursing complexity among inpatient units and medical diagnoses.
- A perfect linear correlation exists between the number of nursing diagnoses on admission and both the length of stay and the mortality rate.
- Some diagnoses are assigned with high frequency, while others are significantly associated with the risk of death or a longer hospital stay and others are simultaneously at high frequency and high risk.

How should the findings be used to influence policy/practice/research/education?

- Understanding the epidemiology of nursing diagnoses may provide detailed information regarding relevant aspects of patient care, with a potentially relevant impact on both the organizational and the clinical aspects of care.
- The number of nursing diagnoses may influence the nursing workload: a high number of nursing diagnoses means a higher nursing complexity in terms of outcome to pursue and interventions to perform.
- The resolution or prevention of high-risk nursing diagnoses should be considered as a treatment priority, leading to personalizing the nursing process and the allocation of staffing resources.

Introduction

The quality of health care, frequently measured using clinical medical data, cannot be assessed effectively without assessing the quality of the nursing care (Maas & Delaney 2004). Unfortunately, nursing is poorly represented in healthcare records (Westra *et al.* 2015). Nursing documentation should help to enhance the efficiency of the decision-making processes in the clinical and management fields by improving the methods of data collection and storage (Juve-Udina 2013). Using nursing data from electronic documentation identifies professional practice and the provision of patient care (Mitchell *et al.* 2009). Electronic health record systems can also increase patient safety, decrease medical errors, improve efficiency and reduce costs (Rosenbloom *et al.* 2006).

Realizing this potential requires a transformation of non-standardized, non-uniform and invisible nursing information into visible, standardized and uniform data (Maas & Delaney 2004). Werley and Lang (1988) proposed the Nursing Minimum Data Set (NMDS) to achieve this aim. The NMDS represents a systematic record of essential standardized nursing data documenting all steps of the nursing process (Sermeus *et al.* 1994, Ranegger *et al.* 2015).

Standardized terms and definitions are required to describe clinical nursing findings and procedures and to ensure appropriate outcomes. Furthermore, a standardized language allows clear, consistent and precise clinical communication (Müller-Staub 2009). Unfortunately, the use of standardized nursing terminologies and information systems is still lacking and not yet the standard method of identifying and measuring the practice of nurses (Thoroddsen *et al.* 2012). The dissemination of electronic information systems does not appear to coincide with the larger amount of data available for research and many clinical information systems do not provide reports on clinical data stored in electronic health records (Head *et al.* 2011, O'Brien *et al.* 2015).

Background

As part of the nursing process, the nursing diagnosis (ND) represents the 'clinical judgement concerning a human response to health conditions/life processes, or a vulnerability for that response, by an individual, family, group or community'; nurses can identify 'problem-focused,' 'health promotion', and 'risk' diagnoses (Herdman 2014). NDs classify patients according to their level of nursing dependency (Halloran & Kiley 1987) and reflect a holistic assessment of patient care needs that affect the amount of nursing interventions, being predictive also for the nursing workload (Halloran 1985, O'Brien-Pallas *et al.* 1997). Dependency observed in basic patient care needs (e.g. feeding and hydration, hygiene, mobility) with related nursing interventions quantify the nursing complexity, which is defined as all dimensions of care expressed as intensity, engagement and nursing work (Galimberti *et al.* 2012). The systematic use of NDs in conjunction with nursing interventions can provide a better measure of nursing complexity because NDs cover wide domains of nursing care (e.g. nutrition, self-care, coping, safety, comfort); they are the current standard terms and are based on the ongoing patient assessment.

A shortage of solid knowledge exists regarding the prevalence and distribution of patient needs among clinical settings and diseases. Only a few studies have been based on large hospital databases that included nursing diagnostic data (Halloran & Kiley 1987, Rosenthal *et al.* 1995, Welton & Halloran 2005, Park *et al.* 2006, O'Brien-Pallas *et al.* 2010, Feng & Chang 2015). Nonetheless, studies such as these are central to improving the knowledge on the epidemiology of NDs. For example, considering the NDs collected at admission after the initial nursing assessment can provide a picture of the most frequent nursing needs in the first hours of care and, consequently, the outcome to achieve and the interventions to perform for a certain category of patients or in a particular care unit. Unfortunately, only a few large studies have analysed the NDs on hospital admission (Rosenthal *et al.* 1992, 1995).

Since several studies have shown that NDs could be associated with key hospital outcomes, such as mortality and length of stay (LOS), the interest regarding the analysis of NDs could be significantly greater (Halloran 1985, Rosenthal *et al.* 1995, O'Brien-Pallas *et al.* 1997, Welton & Halloran 2005). Nursing diagnosis patterns and trends may allow healthcare teams (not just nurses) to make a prognosis and identify the trajectory of care compared with similar patients. The relationship between nursing diagnoses and these outcomes remains uncertain (Maas & Delaney 2004, Müller-Staub *et al.* 2006, Urquhart *et al.* 2009).

Aims

The aims of this study were: 1) to describe the prevalence and distribution of NDs on admission among inpatient units (IUs) and medical diagnoses and 2) to analyse the relationship between the NDs on admission, the patient characteristics and the hospital outcomes.

Research questions

- How many NDs were identified on average for each patient?
- Which NDs were more frequent?
- What were the differences and similarities between the IUs and the medical diagnoses in terms of the prevalence of NDs?
- What is the relationship between the total number of NDs, the patient characteristics (age and sex) and the hospital outcomes (LOS and mortality)?

- What N
higher m

Methods

Design and

This was a p
1547-bed un
had eight dep

Sample/part

Four IUs wer
tion system
All patients
cal (Internal
Oncology, 2
(General Sur
racic Surger
enrolled in t
tal LOS low
patient trans
charged; nur
V64.x ICD9-
hospital for
out because
considered
charged.

Data collecti

Patients were
were prospec
including da
(professional
2012, 2013)

PAI system

The PAI is
nursing care
cess. The PA
age, sex, pr
from the em
and discharg
diagnoses, nu

Each patie
of admission
interviews ar
fied during t

Metodi

- È la sezione di più difficile lettura (e scrittura)
- Fondamentale per una valutazione critica del lavoro
- Consente di capire se lo studio è stato ben condotto e se ci sono bias che possono avere influenzato i risultati
- Dovrebbe riportare:
  - il disegno dello studio
  - le modalità di calcolo della dimensione del campione
  - le modalità di arruolamento
  - i criteri di inclusione e di esclusione dei partecipanti
  - le modalità adottate per evitare le distorsioni
  - le analisi statistiche usate

Support Care Cancer
DOI 10.1007/s00520-014-2478-7

ORIGINAL ARTICLE

The impact of music therapy versus music medicine on psychological outcomes and pain in cancer patients: a mixed methods study

Joke Bradt · Noah Potvin · Amy Kesslick · Minjung Shim · Donna Radl · Emily Schriver · Edward J. Gracely · Lydia T. Komarnicky-Kocher

validating experience for the patient. These experiences offer opportunities to explore and process emotions in a creative process unique from other therapeutic disciplines and facilitate meaning making through music-evoked reflections [7].

Results of a Cochrane systematic review on the use of music interventions with cancer patients indicate that music interventions may have beneficial effects on anxiety, pain, mood, quality of life, and physiological responses [7]. The review authors concluded that more randomized controlled trials (RCTs) are needed to directly compare the effectiveness of MM versus MT interventions with cancer patients so that the impact and clinical role of each can be better understood. The current study was in direct response to this recommendation, namely to (1) compare the impact of MT versus MM interventions on psychological outcomes and pain in cancer patients and (2) enhance understanding of patients' differential experiences of these two types of interventions.

Methods

Design

We firmly believe that research methodology should be driven by research questions rather than by an a priori stance regarding superiority of research method. Therefore, we adhere to pragmatism as our philosophical stance [13]. We used a mixed methods research approach in which both quantitative and qualitative data are gathered and integrated, resulting in interpretations that are grounded in the combined strengths of both data sets [14]. Specifically, we employed a mixed methods intervention design in which qualitative data (i.e., semi-structured exit interviews) were embedded within an RCT [15]. The purpose of the interviews was to (a) bring greater understanding of cancer patients' experience of music interventions and (b) give participants the opportunity to share *in their own words* the impact of the interventions on their well-being.

This study was approved by an Institutional Review Board, and informed consent was obtained from all participants. Thirty-one participants completed two MT sessions and two MM sessions within a 2-week timeframe. Using a list of random numbers, participants were randomized to one of two treatment sequences consisting of two MT sessions followed by two MM sessions or vice versa. The use of sequentially numbered, opaque, sealed envelopes ensured allocation concealment.

Participants

Thirty-one adult cancer patients at an urban hospital were recruited between August 2012 and June 2013. Patients were eligible if they were currently receiving inpatient or outpatient cancer treatment; were proficient in English; and did not have a cognitive impairment, psychotic disorder, or hearing impairment. The mean age was 53.8 years and 67.7 % were female. Demographic characteristics are summarized in Table 1.

As this was considered a pilot study, no a priori sample size was computed. Instead, we anticipated that this study would provide standard deviation estimates to guide future large-scale trials (see Fig. 1 for participant flow).

Interventions

Music therapy MT sessions were provided by a board-certified music therapist and lasted 30 to 45 min each. The aim of the sessions was to help patients manage stress, mood, and pain and to provide psychosocial support. After a brief discussion about current concerns, the music therapist offered live music based on patient needs. She invited participants to sing and/or play an instrument (e.g., xylophone and small percussion instruments) along to a familiar song or improvised melody. These experiences were followed by additional songs, co-created instrumental or vocal improvisations, song-writing, or music-guided breathing exercises. The therapist provided ample opportunity for verbal processing of emotions and thoughts evoked by the music.

Music medicine At the start of the study, participants were asked to list their music preferences on a demographic information sheet. Based on this information, we created individualized playlists. The music therapist met with each participant at the start of the MM session to deliver an iPod with the patient's playlist. The music therapist made sure the patient was able to operate the iPod, but no further assessment took place. Participants were asked not to engage in other activities while the music played. The music therapist then left the room. MM sessions lasted 30–45 min.

Table 1 Participant characteristics (n=31)

	N (%)
Age (M±SD, range)	53.8±13.84, 32–88 years
Gender	
Female	21 (67.7)
Ethnicity	
Black	23 (74.2)
Caucasian	6 (19.4)
Asian	1 (3.2)
Other	1 (3.2)
Marital	
Married	7 (22.6)
Non-married	10 (32.3)
Widower/widow	6 (19.4)
Divorced/separated	5 (16.1)
Other	3 (9.6)
Education	
High school or less	24 (77.4)
College/university	7 (22.6)
Type of cancer	
Breast	6 (19.4)
Gastrointestinal	3 (9.7)
Gynecological	3 (9.7)
Head and neck	3 (9.7)
Hematologic	7 (22.6)
Lung	4 (12.9)
Other	5 (16)
Recurrence of cancer	
No (first time)	22 (71)
Yes (second time or more)	8 (25.8)
Not reported	1 (3.2)
Patient type	
Outpatient	22 (71)
Inpatient	9 (29)

We minimized expectation effects of participants throughout the study by referring to both treatment conditions as music sessions rather than referring to one intervention as music therapy.

Measures and data collection

Mood, anxiety, and relaxation were measured with a visual analogue scale (VAS), a 100-mm line; the length of which represents a continuum of an experience such as mood. Pain intensity was measured by means of an 11-point numeric rating scale (0–10) [16].

All participants were invited to participate in an audio-recorded semi-structured, open-ended exit interview. Interview questions focused on the participants' experiences of the music sessions in general and about their differential experiences of the MT and MM sessions. Participants were also asked which of these they would like to receive for future treatments. A blinded outcome assessor collected the quantitative outcome data immediately before and after each music session. After the final session, the outcome assessor conducted the exit interview.

Data analysis

Quantitative analysis Data were entered into RedCap [17] and exported to SAS/STAT® software for analysis. Average pre- and posttest scores were computed for the two sessions of each treatment condition. We utilized these averages for comparisons within and between conditions. In the event of skewed data, Wilcoxon rank sum tests were used to test the within-condition differences. Otherwise, paired t tests were used. Paired t tests on the difference scores were used to test for between-condition differences.

Qualitative analysis The interviews were transcribed verbatim and reviewed for accuracy. The transcripts were imported into MAXQDA 11 [18] and analyzed by two coders (NP, JB) using theoretical thematic analysis procedures as outlined by Braun and Clarke [19]. Theoretical thematic analysis is aimed at identifying and analyzing patterns driven by an a priori theoretical framework or specific research questions. The coding was guided by the following research questions: (1) What do participants report as treatment benefits or harms? and (2) How do they describe their (differential) experiences of the two types of music interventions? Themes were identified using a semantic approach [19] in which themes are derived from "the explicit meaning of the data and the analyst is not looking for anything beyond what a participant has said" [19] (p. 84).

Integration of data sets After completion of the quantitative and qualitative data analysis, the two data sets were compared to examine (dis)congruence of the findings. In addition, we created a joint display [15] of quantitative and qualitative findings to examine differential experiences of participants whose quantitative data profile indicated much greater benefits in MT than in MM or vice versa.

Results

Quantitative results

The quantitative data indicate that the MT and MM sessions were equally effective in improving anxiety, mood, relaxation, and pain. There was no statistically significant difference between the conditions for these outcomes (Table 2).

Contents lists available at ScienceDirect

International Journal of Nursing Studies

journal homepage: www.elsevier.com/locate/

Nurse practitioner led pain management the day after ca
randomised controlled trial and follow-up study

Anthony Schoenwald[a,b,c,*], Carol Windsor[b,c], Edward Gosden[c], Clint Dou

3. Methods

3.1. Participants

Potential participants were identified in the booking record of scheduled deliveries from July 2013 to December 2014. Following an initial telephone call, participants who indicated a willingness to take part in the trial were mailed information and consent forms. Eligible women were required to be at least 18 years of age and scheduled for elective caesarean section. Only English speaking women were considered for inclusion. Exclusion criteria included contraindications to spinal analgesia, a history of any type of chronic pain, opioid tolerance, and substance abuse. Potential participants were also excluded if they reported adverse reactions to any drugs or interventions planned for use in the trial such as intrathecal morphine and oral analgesics. A final exclusion criterion was women with a diagnosis of herpes simplex viral infection as concomitant administration of intrathecal morphine can result in spread of the infection.

3.2. Sample size calculation

A sample size was calculated using G*Power version 3 based on the ability of an independent samples *t*-test to detect a mean difference of 10 mm on a 0–100 mm visual analogue scale between two groups. The standard deviation used in the calculation (18 mm) was reported in previous trials (Davis et al., 2006; McDonnell et al., 2010). A confidence level of 95% ($p < .05$) and power of 80% were used. The calculation gave a sample size of 104, that is, two equal groups of 52 women. The sample size was increased by 15% to address the possibility that non-parametric statistics might have to be used because of non-normality of the dependent variable. A further increase of 10% was added to allow for attrition, giving an overall sample size of 130 participants.

3.3. Randomisation

The sequence was generated by an independent researcher and concealment of group allocation was based on the sequentially numbered opaque sealed envelopes technique. Each sequentially numbered envelope contained the treatment group allocation and instructions that remained concealed until given to the anaesthetist on the day of surgery. Envelopes were prepared by another independent researcher and the sequential number corresponded to the research participant number on the master allocation list (allocation ratio 1:1).

3.4. Blinding

The process blinded anaesthetists and other perioperative staff until the envelopes were opened prior to surgery. The nurse practitioner was also blinded to treatment allocation until the intervention commenced the day after surgery. For the follow-up interviews, a research assistant was blinded to treatment allocation. Only the sequence number was placed on the completed questionnaires.

3.5. Care given to all participants

The anaesthesiology director arranged for all participants to be administered hyperbaric bupivacaine (0.5%), morphine (100 mcg), and fentanyl (20 mcg) via the intrathecal route. Paracetamol (one gram) and intravenous parecoxib (40 mg) were also administered. For post-operative pain management, oral paracetamol (one gram) was administered four times per day commencing at 18:00 h on the day of surgery and oral ibuprofen (400 mg) three times per day for three days commencing at 08:00 h on the first postoperative day.

3.6. Intervention

The intervention integrated treatment with oral oxycodone alongside supportive care and education about pain management. Before 8:00 on the day after surgery, the nurse practitioner engaged participants in a discussion about their experience and explained the scheduled doses of immediate-release oxycodone at 8:00 h (10 mg), 14:00 h (5 mg), and 20:00 h (5 mg). Prescribed by anaesthetists in the operating suite, these scheduled doses were necessary for ethical and anaesthetic department support for the trial. It was conveyed that these doses could be refused and unscheduled oxycodone or tramadol could be requested at any time. The nurse practitioner communicated to participants that they had control over these decisions. Another key component of the intervention was to discuss the effectiveness of immediate-release oxycodone and how it could reduce pain interference. The discussion also aimed to identify any misconceptions participants had regarding the pharmacology and safety of oxycodone, and to provide education to address any issues. The final stages of the intervention involved follow-up of participants throughout the day at 11:00 and 14:00 h. The nurse practitioner assessed participant reports of pain using a 0–10 verbal rating scale and, if analgesia was inadequate, the nurse practitioner supported maternal control and request for additional pain relief. Each review lasted approximately 5–10 min.

3.7. Standard conditions (control group)

The control group was prescribed a standard postoperative dose of 10 mg of controlled-release oxycodone commencing at 08:00 h the day after surgery and continuing every 12 h for two days. Control group participants received one review by the acute pain service made up of an anaesthetist and a registered nurse.

3.8. Outcome measures

3.8.1. Baseline data

Prenatal data included age, ethnicity, level of education, parity, gestation in weeks, number of previous caesareans, and body mass index. The Pain Catastrophising Scale (Sullivan et al., 1995) was used to screen for catastrophic thoughts prior to admission to hospital. It is a 13-item scale and participants responded to statements about thoughts or feelings when experiencing pain or past painful experiences (Sullivan et al., 1995). Maternal depression was also measured prior to hospitalisation with the Edinburgh Postnatal Depression Scale (Cox et al., 1987). The scale is widely used as a screening tool for maternal depression (Cox et al., 1987; Rowe et al., 2008; Swalm et al., 2010). It contains 10 items scored in a range of 0–3 with higher scores signifying emotional distress. The validity and reliability of the tool has been demonstrated by comparing it with other depression scales during and after pregnancy (Ji et al., 2011). Pre-intervention consumption of oxycodone and tramadol within six hours of the commencement of the intervention was recorded as was the dose and time of administration of intrathecal morphine.

3.8.2. Primary outcome

The visual analogue scale was used to evaluate pain intensity where participants marked a 100 mm line with the anchors 'no pain' and 'the worst pain imaginable.' The validity and reliability of the scale in clinical research has been well established (Breivik et al., 2008; Kahl and Cleeland, 2005). In this study, participants recorded scores at rest and on sitting for the first four hours starting at 8:00 h. Pain scores were also recorded at rest and on movement 24 h following the intervention.

3.8.3. Secondary outcomes

The Patient Global Impression of Change scale was also completed over the first four hours after the first scheduled dose of oxycodone. The scale is a global measure with 7 categories designed to evaluate pain relief over time (O'Connor and Dworkin, 2011). Categories range from 'very much worse' pain to 'very much improved'. Reduced pain intensity has been correlated with improved ratings on the scale (Elfving et al., 2016; Geisser et al., 2010). No studies have used this scale to measure the effects of an intervention for caesarean pain.

The modified Brief Pain Inventory (Akyol et al., 2009) was used as a measure of pain interference. Participants recorded pain interference scores on 0–10 numerical rating scales at 20:00 h the day after surgery. Items on the scale included the impact of pain on coughing and breathing, making the modified scale suitable for use in the context of postoperative pain (Akyol et al., 2009; Atkinson et al., 2010).

Total opioid doses were calculated for two postoperative days. The doses included scheduled plus additional doses of oxycodone and tramadol requested by participants. Opioid-induced nausea, pruritus, and drowsiness were evaluated using 0–100 mm visual analogue scale scores with the anchors 'none' to 'intolerable'. Similar scales have been used in trials evaluating side effects after caesarean (McDonnell et al., 2010).

Maternal perception of control over pain management was also evaluated 24 h following the intervention. A 0–100 mm scale was used with the anchors of 'none' and 'complete' for the question 'how much control did you have over your pain management?'. The scale was adapted from a study on the relationship between perceived control over pain management and satisfaction with the childbirth experience (McCrea and Wright, 1999). Scales to measure perception of control in childbirth situations have been used in previous research (Ford and Ayres, 2008) but have not been used to compare interventions for caesarean pain.

3.8.4. Follow-up at three months

The Graded Chronic Pain Scale – Version Two (Von Korff, 2011) was used to determine pain intensity and disability three months after surgery. This eight-item scale allows for evaluation of pain intensity, pain interference, and pain persistence by providing numerical rating scores from 0 to 10 (Von Korff, 2011). Three items for pain intensity give a score out of 30 and disability scores are added to determine a score ranging from 0 to 40. The scale is used to grade chronic pain and disability ranging from Grade I (low intensity and interference) to Grade IV (severe pain interference). Recall of pain reports over three months using this scale have demonstrated consistency with diary entries over the same period ($r = 0.80$) (Von Korff, 2011). In the follow-up interviews, the same postnatal depression scale and modified brief pain inventory were used as in the postoperative phase.

3.8.5. Ethical considerations

The trial was registered with the Australian and New Zealand Registry of Clinical Trials (Registration: ACTRN12613000076774) and ethical approval was obtained from the hospital human research ethics committee (HREC/13/QWMS/8). The research was conducted in accordance with the principles of the Declaration of Helsinki embedded in the National Statement for the Conduct of Human Research in Australia (National Health and Medical Research Council, 2007). As noted, approval for this trial was partially dependent on the intervention group receiving the same total dose of scheduled oxycodone as the control group because some medical staff perceived that midwives may not have provided women with appropriate access to requested oxycodone. The research protocol and all data collection methods were approved by the human research ethics committee.

3.8.6. Data collection

Baseline data were collected by the first author prior to commencement of the trial. Participants either mailed or completed the baseline questionnaire on the day of admission. Beginning at 8:00 h the morning after surgery, participants recorded hourly scores for pain intensity and global impression of change. On the same evening at 20:00 h, participants rated their pain interference and opioid-induced side effects. Finally, pain scores on the second day were assessed at 8:00 h. Calculations of opioid consumption were carried out by the first author on the day of discharge from hospital. These calculations were later verified by a research assistant who also conducted telephone interviews three months after the date of surgery.

3.8.7. Data analysis

The IBM SPSS Statistics version 22 (IBM Corporation, Armonk, NY, USA) was used for data analysis. For complex analyses of 0–100 mm scores for pain, a linear mixed regression model was applied because it has been suggested as appropriate for determining associations between multiple variables and for responses that display a wide pattern of variation (Demidenko, 2013; Shin, 2009). Mixed models analysis is also more suitable than repeated measures ANOVA as the analytical methods make more efficient use of data when a proportion is missing (Cleophas et al., 2009; Demidenko, 2013; Shin, 2009). The patient global impression of change scale was analysed by binary logistic regression. Mann Whitney *U* tests were used to determine the differences in pain interference scores, opioid consumption, and opioid-induced side effects. For the follow-up, descriptive data were reported using median scores and interquartile ranges. Also, a grade for chronic pain was calculated for each participant as described in the Graded Chronic Pain Scale (Von Korff, 2011). Multiple linear regression models were constructed to explore associations between variables affecting pain outcomes over three months.

3.8.8. Interim analysis and stopping guidelines

The ethics application contained stopping guidelines and the criteria were medical emergency caused by the intervention, severe intractable pain, unexplained pain intensity, pain unable to be managed under the nurse practitioner scope of practice, persistent opioid-induced side effects greater than 40 mm despite treatment, withdrawal of consent by the participant, or allergic drug reaction due to trial analgesics. Grounds for cessation of the trial were if greater than 30% of participants reported greater than 40 mm for drowsiness, nausea, or pruritus. An interim analysis after 60 participants demonstrated no participant complaints, no increase in adverse drug effects, and no increase in pain from the intervention when compared to the control group (standard care).

4. Results

The total sample included 131 women randomised to either the intervention ($n = 65$) or control group ($n = 66$). The final sample consisted of 61 participants in each of the control and intervention groups as four participants from the intervention group and five from the control group left the hospital without completing any of the questionnaires (Fig. 1). For the follow-up analyses, results were generated based on the combined sample of control and intervention participants ($n = 85$).

4.1. Baseline results

The demographic and antenatal characteristics of both groups are shown in Table 1. Over half of all participants (50.8%) underwent their second caesarean delivery and there were slight differences in Caucasian participants, 85.2% for the control group and 98.4% for participants receiving the intervention. The mean time from injection of intrathecal morphine to 8:00 h the day after was 20 h ($p = 0.710$). Both groups differed in the total dose of oxycodone administered within six hours of the start of the intervention and control treatments. Fifteen participants in the control group (25%) received 5–20 mg of immediate-release oxycodone compared to five participants (8.2%) in the intervention group who received only 5–10 mg ($p = 0.032$). For tramadol, 21 participants (34.4%) in the intervention group required 50–100 mg compared to 10 (16.7%) in the control group ($p = 0.073$).

Risultati

- Devono essere illustrati in maniera chiara, completa e attendibile
- In questa sezione si trovano gli elementi oggettivi per valutare l'attendibilità dello studio
- I risultati devono rispondere alle domande iniziali per cui è stata condotta la ricerca e devono dar conto momento per momento della popolazione coinvolta (es. eventuali perdite di pazienti)

Contents lists available at ScienceDirect

International Journal of Nursing Studies

journal homepage: www.elsevier.com/locate/ijns

Nurse practitioner led pain management the day after caesarean section: A randomised controlled trial and follow-up study

Anthony Schoenwald[a,b,c,*], Carol Windsor[b,c], Edward Gosden[c], Clint Douglas[b,c]

interviews three months after the date of surgery.

3.8.7. Data analysis

The IBM SPSS Statistics version 22 (IBM Corporation, Armonk, NY, USA) was used for data analysis. For complex analyses of 0–100 mm scores for pain, a linear mixed regression model was applied because it has been suggested as appropriate for determining associations between multiple variables and for responses that display a wide pattern of variation (Demidenko, 2013; Shin, 2009). Mixed models analysis is also more suitable than repeated measures ANOVA as the analytical methods make more efficient use of data when a proportion is missing (Cleophas et al., 2009; Demidenko, 2013; Shin, 2009). The patient global impression of change scale was analysed by binary logistic regression. Mann Whitney *U* tests were used to determine the differences in pain interference scores, opioid consumption, and opioid-induced side effects. For the follow-up, descriptive data were reported using median scores and interquartile ranges. Also, a grade for chronic pain was calculated for each participant as described in the Graded Chronic Pain Scale (Von Korff, 2011). Multiple linear regression models were constructed to explore associations between variables affecting pain outcomes over three months.

3.8.8. Interim analysis and stopping guidelines

The ethics application contained stopping guidelines and the criteria were medical emergency caused by the intervention, severe intractable pain, unexplained pain intensity, pain unable to be managed under the nurse practitioner scope of practice, persistent opioid-induced side effects greater than 40 mm despite treatment, withdrawal of consent by the participant, or allergic drug reaction due to trial analgesics. Grounds for cessation of the trial were if greater than 30% of participants reported greater than 40 mm for drowsiness, nausea, or pruritus. An interim analysis after 60 participants demonstrated no participant complaints, no increase in adverse drug effects, and no increase in pain from the intervention when compared to the control group (standard care).

4. Results

The total sample included 131 women randomised to either the intervention ($n = 65$) or control group ($n = 66$). The final sample consisted of 61 participants in each of the control and intervention groups as four participants from the intervention group and five from the control group left the hospital without completing any of the questionnaires (Fig. 1). For the follow-up analyses, results were generated based on the combined sample of control and intervention participants ($n = 85$).

4.1. Baseline results

The demographic and antenatal characteristics of both groups are shown in Table 1. Over half of all participants (50.8%) underwent their second caesarean delivery and there were slight differences in Caucasian participants, 85.2% for the control group and 98.4% for participants receiving the intervention. The mean time from injection of intrathecal morphine to 8:00 h the day after was 20 h ($p = 0.710$). Both groups differed in the total dose of oxycodone administered within six hours of the start of the intervention and control treatments. Fifteen participants in the control group (25%) received 5–20 mg of immediate-release oxycodone compared to five participants (8.2%) in the intervention group who received only 5–10 mg ($p = 0.032$). For tramadol, 21 participants (34.4%) in the intervention group required 50–100 mg compared to 10 (16.7%) in the control group ($p = 0.073$).

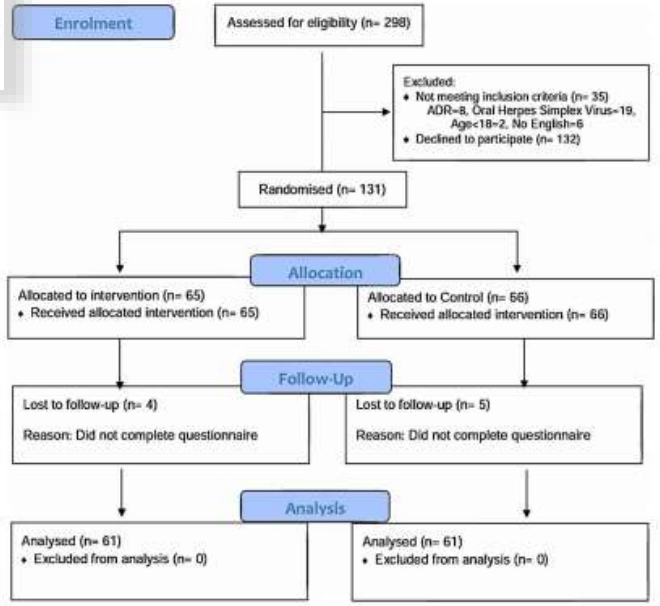


Fig. 1. Consort diagram of participant flow.

Table 1
Baseline Data.

Measure	n	Control	Intervention	p value (control vs. intervention)
Age Mean (SD)	119	29.9 (5.6)	30.2 (5.9)	0.822[a]
Body Mass Index Mean (SD)	115	34.9 (7.8)	33.9 (7.2)	0.499[a]
Ethnicity	122			0.008[b]
Caucasian		52 (85.2%)	60 (98.4%)	
Other		9 (14.8%)	1 (1.6%)	
Education	122			0.957[b]
< High School		5 (8.2%)	5 (8.2%)	
High School		49 (80.3%)	50 (82.0%)	
University		7 (11.5%)	6 (9.8%)	
Depression Mean (SD)	113	4.4 (4.3)	4.2 (3.3)	0.790[a]
Pain Catastrophising Score Mean (SD)	97	14.1 (11.2)	11.3 (9.9)	0.189[a]
Previous Caesarean	122			0.695[b]
First Caesarean		13 (21.3%)	13 (21.3%)	
Second Caesarean		29 (47.5%)	33 (54.1%)	
> 2 Caesareans		19 (31.1%)	15 (24.6%)	
Parity	122			0.030[b]
Nulliparous		0 (0%)	0 (0%)	
Primiparous		11 (18%)	24 (39.3%)	
Multiparous		50 (82.0%)	37 (60.7%)	

[a] Independent samples *t*-test.
[b] Chi Square Test of Independence.

4.2. Primary outcomes

Due to non-linear response curves, pain scores were analysed by linear mixed models with spline regression, with a priori determination of the knots based on inflections in the mean response curve. For resting pain, spline one covered the response from 8:00 to 9:00 h, spline two the response from 9:00 to 12:00 h, and spline three the response from 12:00 to 8:00 h the following morning. Spline one for pain on sitting covered the period from 8:00 to 10:00, spline two 10:00 to 12:00, and spline three 12:00 to 8:00 h the following morning.

Variables were tested by univariate regression followed by stepwise addition in ascending order of univariate *p* values. The final models demonstrated no statistical significance for the intervention over 24 h for pain at rest ($p = 0.40$, 95% CI −4.8 mm, 11.9 mm) or pain on sitting/moving ($p = 0.561$, 95% CI −15.2 mm, 8.3 mm). At the specific time of 9:00 h for pain at rest, mean pain for those who received the intervention decreased by 5.3 mm ($p = 0.050$, 95% CI −10.7, 0.0). For pain on sitting at 10:00 h, mean pain decreased by 6.1 mm ($p = 0.063$, 95% CI: −12.6 mm, 0.3 mm). Other time-points or splines were not analysed as pain intensity scores were highly variable and this created computational difficulties. Mean pain scores are presented in Figs. 2 and 3.

The final regression model for pain at rest showed that pain catastrophising and previous caesarean deliveries were associated with greater pain intensity over 24 h. For every previous caesarean section, mean pain intensity at rest for all participants increased by 7.3 mm ($p = 0.004$, 95% CI 2.4, 12.0) and for every one-point increase in pain catastrophising, mean pain at rest increased by 0.4 mm ($p = 0.023$, 95% CI 0.1, 0.8). These results were statistically significant.

4.3. Secondary outcomes

From 8:00 h the day after caesarean section, the intervention group reported 'much improved' or 'very much improved' global change in pain relief over three hours with greater odds than the control group ($p = 0.014$, OR = 2.5, 95% CI 1.2, 5.3). At 20:00 h on the same day, the intervention group reported less total pain interference than the control group ($U = 992$, $p = 0.029$). The intervention group also experienced less pain interference on general activity ($U = 1017$, $p = 0.042$), walking ($U = 925$, $p = 0.008$), and coughing ($U = 1011$, $p = 0.037$), as presented in Table 2. The differences here were also statistically significant.

Participants in the intervention group were administered less total oxycodone (median = 30, IQR = 20–25 mg) than the control group (median = 30, IQR = 30–40 mg) over 28 h ($U = 989$, $p = 0.001$). There was no difference between groups in terms of postoperative tramadol consumption over 28 h ($U = 1565$, $p = 0.989$). No statistically significant differences were found between groups in terms of subjective reports of nausea ($U = 1333$, $p = 0.768$), itching ($U = 1367$, $p = 0.944$), or drowsiness ($U = 1326$, $p = 0.739$). Where zero represented no control over pain management and 100 mm complete control, scores were slightly lower for the control group (54.3 ± 23.7) compared to the intervention group (60.1 ± 26.8). The difference was not statistically significant ($t = -1.10$, $p = 0.273$, 95% CI −16.2 mm, 4.6 mm).

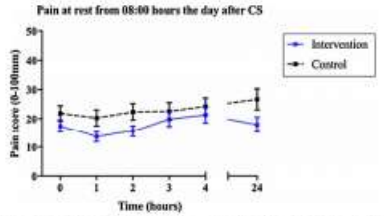


Fig. 2. Pain at rest (means and standard errors) from 8:00 to 12:00 h the day after and then at 8:00 h on the second postoperative morning.

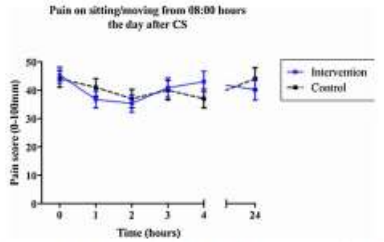


Fig. 3. Pain on sitting (means and standard errors) from 8:00 to 12:00 h on the first postoperative day and then movement pain at 8:00 h on the second postoperative morning.

Table 2
Pain interference recorded at 20:00 on the first postoperative day (medians and interquartile ranges).

Measure	Control n = 49	Intervention n = 54	Mann Whitney U	P value
Activity	5 [3,7]	4 [2,7]	1017	0.042
Mood	2 [1,4]	1 [0,3]	1069	0.087
Walking	5 [3,8]	3 [2,7]	925	0.008
Relationships	0 [0,2]	0 [0,1]	1208	0.379
Coughing	7 [2,10]	4 [1,8]	1011	0.037
Breathing	0 [0,3]	0 [0,1]	1195	0.329
Concentration	1 [0,4]	1 [0,2]	1264	0.680
Enjoyment	1 [0,4]	1 [0,3]	1173	0.295
Total	25 [11,39]	15 [8,34]	992	0.029

4.4. Three-month follow-up

Five participants (5.9%) reported pain scores of greater than three out of 10 at the time of the telephone interview. Overall, participants reported a median score of four days of pain over three months. Two participants (2.4%) reported persistent pain for greater than 40 days. There were no statistically significant differences in between the intervention and control groups across these outcomes. Every point increase in postnatal depression from baseline was associated with an increase in total pain interference at three months of approximately one point ($p < 0.001$, $\beta = 1.1$, 95% CI 1.0, 1.1). Elevated postnatal depression scores were also associated with one more day of pain for every point increase ($p < 0.001$, $\beta = 1.0$, 95% CI 1.1, 1.8). In relation to the graded chronic pain scale, 87.1% of participants were graded as low pain intensity and low interference (Grade I). Three participants (3.5%) were graded as high pain intensity with little or no interference (Grade II) and another three participants (3.5%) were graded as moderate interference (Grade III). Five participants (5.9%) were graded as severe pain interference (Grade IV).

5. Discussion

In terms of the first research question, the primary study outcome was not significantly different between the two groups. Nonetheless, an important finding of this phase of the trial was the variability in individual responses in relation to pain intensity scores over time, so much so that the slopes for splines two and three could not be analysed in the linear mixed effects model. This underscores the need to recognise individual variability in response to pain when formulating and evaluating pain interventions. Thus, reduced pain intensity scores alone may not be the only reliable indicator of improved analgesia. Farrar et al., (2010) argued that global categorical responses are equally important and more appropriate because of variance in the way individuals report pain intensity. Furthermore, others have suggested that global impression of change scales can be more responsive to treatment effects for postoperative pain interventions (Jensen et al., 2005). In this study, clinically meaningful global impression of change at 11:00 h contrasts with the results for pain intensity scores (O'Connor and Dworkin, 2011; Turk and Melzack, 2011). Overall, this perceived change may have been enough to reduce pain interference and thus made it easier for some women to mobilise and perform other maternal functions.

Pain interference was reduced as reported by maternal recall of the impact of pain over 12 h during the day after surgery. The intervention may have enhanced the ability of participants to mobilise as this was a key component of the discussion alongside information about the time to maximum concentration of immediate-release oxycodone. Furthermore, additional doses of oxycodone and tramadol throughout this day may have lessened the impact of pain. This could have been the expectation of many participants from the intervention group because a goal of the intervention was to enable greater maternal control and participation in the management of opioid analgesics.

The intervention was designed to use education and supportive follow-up care to enable greater control and participation by women in pain management. While no studies have evaluated this approach to care following caesarean section, there is some evidence of the benefits of these strategies in other surgical contexts (Kol et al., 2014; Sayin and Aksoy, 2012; Wong et al., 2010; Zoega et al., 2014). The difficulty of interpreting previous work in this area is because of lack of detail on formulations and doses of analgesics administered to participants alongside these strategies. Furthermore, participation and control over pain management are complex issues. A comprehensive approach to pain must consider that not all patients desire the same degree of control or level of participation (McTier et al., 2014). Nonetheless, the predominant view is that analgesics will work better if there exists shared decision-making and a positive relationship between patients

Discussione

- È la sezione più soggettiva di un articolo
- Aiuta a capire i risultati secondo l'interpretazione degli autori
- Le affermazioni dei ricercatori devono essere coerenti con i dati riportati nei Risultati

Limiti

- Indicare i punti deboli e i difetti di uno studio per consentire al lettore di interpretare risultati e conclusioni nella giusta luce

Contents lists available at ScienceDirect

International Journal of Nursing Studies

journal homepage: www.elsevier.com/locate/ijnurstu

Nurse practitioner led pain management the day after caesarean section: A randomised controlled trial and follow-up study

Anthony Schoenwald[b,h,i,*], Carol Windsor[b,i], Edward Gosden[c], Clint Douglas[b,i]

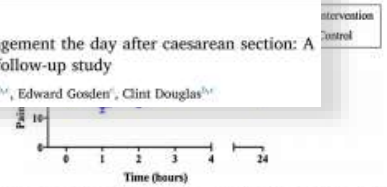


Fig. 2. Pain at rest (means and standard errors) from 8:00 to 12:00 h the day after and then at 8:00 h on the second postoperative morning.

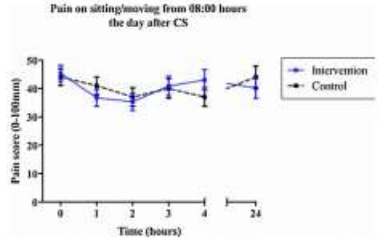


Fig. 3. Pain on sitting (means and standard errors) from 8:00 to 12:00 h on the first postoperative day and then movement pain at 8:00 h on the second postoperative morning.

Table 2
Pain interference recorded at 20:00 on the first postoperative day (medians and interquartile ranges).

Measure	Control n = 49	Intervention n = 54	Mann Whitney U	P value
Activity	5 [3,7]	4 [2,7]	1017	0.042
Mood	2 [1,4]	1 [0,3]	1069	0.087
Walking	5 [3,8]	3 [2,7]	925	0.008
Relationships	0 [0,2]	0 [0,1]	1208	0.379
Coughing	7 [2,10]	4 [1,8]	1011	0.037
Breathing	0 [0,3]	0 [0,1]	1195	0.329
Concentration	1 [0,4]	1 [0,2]	1264	0.680
Enjoyment	1 [0,4]	1 [0,3]	1173	0.295
Total	25 [11,39]	15 [8,34]	992	0.029

the intervention group reported less total pain interference than the control group ($U = 992$, $p = 0.029$). The intervention group also experienced less pain interference on general activity ($U = 1017$, $p = 0.042$), walking ($U = 925$, $p = 0.008$), and coughing ($U = 1011$, $p = 0.037$), as presented in Table 2. The differences here were also statistically significant.

Participants in the intervention group were administered less total oxycodone (median = 30, IQR = 20–25 mg) than the control group (median = 30, IQR = 30–40 mg) over 28 h ($U = 989$, $p = 0.001$). There was no difference between groups in terms of postoperative tramadol consumption over 28 h ($U = 1565$, $p = 0.989$). No statistically significant differences were found between groups in terms of subjective reports of nausea ($U = 1333$, $p = 0.768$), itching ($U = 1367$, $p = 0.944$), or drowsiness ($U = 1326$, $p = 0.739$). Where zero represented no control over pain management and 100 mm complete control, scores were slightly lower for the control group (54.3 ± 23.7) compared to the intervention group (60.1 ± 26.8). The difference was not statistically significant ($t = -1.10$, $p = 0.273$, 95% CI −16.2 mm, 4.6 mm).

4.4. Three-month follow-up

Five participants (5.9%) reported pain scores of greater than three out of 10 at the time of the telephone interview. Overall, participants reported a median score of four days of pain over three months. Two participants (2.4%) reported persistent pain for greater than 40 days. There were no statistically significant differences in between the intervention and control groups across these outcomes. Every point increase in postnatal depression from baseline was associated with an increase in total pain interference at three months of approximately one point ($p < 0.001$, $\beta = 1.1$, 95% CI 1.0, 1.1). Elevated postnatal depression scores were also associated with one more day of pain for every point increase ($p < 0.001$, $\beta = 1.0$, 95% CI 1.1, 1.8). In relation to the graded chronic pain scale, 87.1% of participants were graded as low pain intensity and low interference (Grade I). Three participants (3.5%) were graded as high pain intensity with little or no interference (Grade II) and another three participants (3.5%) were graded as moderate interference (Grade III). Five participants (5.9%) were graded as severe pain interference (Grade IV).

5. Discussion

In terms of the first research question, the primary study outcome was not significantly different between the two groups. Nonetheless, an important finding of this phase of the trial was the variability in individual responses in relation to pain intensity scores over time, so much so that the slopes for splines two and three could not be analysed in the linear mixed effects model. This underscores the need to recognise individual variability in response to pain when formulating and evaluating pain interventions. Thus, reduced pain intensity scores alone may not be the only reliable indicator of improved analgesia. Farrar et al., (2010) argued that global categorical responses are equally important and more appropriate because of variance in the way individuals report pain intensity. Furthermore, others have suggested that global impression of change scales can be more responsive to treatment effects for postoperative pain interventions (Jensen et al., 2005). In this study, clinically meaningful global impression of change at 11:00 h contrasts with the results for pain intensity scores (O'Connor and Dworkin, 2011; Turk and Melzack, 2011). Overall, this perceived change may have been enough to reduce pain interference and thus made it easier for some women to mobilise and perform other maternal functions.

Pain interference was reduced as reported by maternal recall of the impact of pain over 12 h during the day after surgery. The intervention may have enhanced the ability of participants to mobilise as this was a key component of the discussion alongside information about the time to maximum concentration of immediate-release oxycodone. Furthermore, additional doses of oxycodone and tramadol throughout this day may have lessened the impact of pain. This could have been the expectation of many participants from the intervention group because a goal of the intervention was to enable greater maternal control and participation in the management of opioid analgesics.

The intervention was designed to use education and supportive follow-up care to enable greater control and participation by women in pain management. While no studies have evaluated this approach to care following caesarean section, there is some evidence of the benefits of these strategies in other surgical contexts (Kol et al., 2014; Sayin and Aksoy, 2012; Wong et al., 2010; Zoega et al., 2014). The difficulty of interpreting previous work in this area is because of lack of detail on formulations and doses of analgesics administered to participants alongside these strategies. Furthermore, participation and control over pain management are complex issues. A comprehensive approach to pain must consider that not all patients desire the same degree of control or level of participation (McTier et al., 2014). Nonetheless, the predominant view is that analgesics will work better if there exists shared decision-making and a positive relationship between patients and clinical staff (Australian Pharmaceutical Advisory Council, 2005; McTier et al., 2014).

Broader aspects of analgesic administration may have hindered the ability of the intervention to shift perceived control to women. Participants were not able to regulate the types or doses of all analgesics used. For example, all participants were administered scheduled doses of non-opioid analgesics as part of the design of this study. Participants were not, however, given power over decision-making around control over other analgesic types such as paracetamol or non-steroidal anti-inflammatory drugs. Other types of non-steroidal anti-inflammatory drugs could have been offered to participants as could control over oxycodone doses. Thus, opportunities to individualise other therapies were not considered and some women may have perceived that clinical staff had more control. Other researchers have suggested that promoting greater control over caesarean pain is extremely difficult due to this issue (McCrea and Wright, 1999). Hence, the intervention in this study may not have gone far enough in promoting maternal control and participation in the pain management plan. The approach could be improved by offering participants more decision-making power over analgesics and better supporting the preferences of women by commencing the relationship prior to hospitalisation.

That acute caesarean pain is a complex biopsychosocial experience is supported by this study which identified many factors that shaped the experience. For example, the greater number of previous caesarean deliveries was predictive of more postoperative pain. This may be partly explained by the argument that scar hyperalgesia can result from previous Pfannenstiel incision and make women more sensitive to pain (Loos et al., 2008; Ortner et al., 2013). Furthermore, an experience of poor analgesia can lead to an intense fear of pain prior to a subsequent delivery and result in catastrophic thoughts about pain (Keogh et al., 2005). Prenatal pain catastrophising was associated with more postoperative pain and this is consistent with previous research (Flink et al., 2009; Strulov et al., 2007). Pain catastrophising has been shown to be a potent factor that increases postoperative pain in many other surgical models (Masselin-Dubois et al., 2013) and may interact with depression to worsen the situation (Dehghani et al., 2014). Perioperative depression has been associated with postoperative pain in previous research (Andersen et al., 2004; Hobson et al., 2005; Keogh et al., 2005; Lou and Kong, 2012; Saunders et al., 2006) but not in this study. A possible explanation is that mean prenatal depression scores were not indicative of significant depression. The affective components of caesarean pain appear to have been manifest after discharge from hospital. The follow-up phase of this trial, therefore, has contributed knowledge to the problem of chronic pain after caesarean section.

The International Association for the Study of Pain estimates that the incidence of severe chronic pain after caesarean section is 4% (IASP, 2011) and the results of this study further describe the experience. Three months after surgery, moderate pain was reported by approximately 6% of participants. Bonnal and others have reported similar results (Bonnal et al., 2016). These findings suggest that, for most women, pain at three months had subsided. The follow-up interviews in this study also found that most women experienced a median of four days of pain over three months. However, for those who reported more pain interference and more days of pain, the development of postnatal depression was a strong associated factor. This finding supports the proposition that the onset of depression after caesarean section can lead to chronic pain (Lavand'homme, 2013). The finding is important because a grade of serious disability was the outcome for a small subset of women in the study. Hence, in the context of acute pain, the study contributes to knowledge about the association between postnatal depression and pain outcomes following caesarean section and highlights the need for models of care that can address such problems.

5.1. Limitations

The small sample size makes it difficult to apply the results to the general population and it is also acknowledged that the integrative nature of the intervention made it difficult to blind participants to the formulation of oxycodone. The impact of pain on breastfeeding and maternal satisfaction was also not included. During the preparation phase, these issues were considered because they have been measured in cohort studies. They were excluded from this study because of the risk of increased burden on participants that was an expressed concern of the human research ethics committee.

5.2. Implications for nursing practice

The results of this study have the potential to influence how acute pain is measured by highlighting individual variance in response to acute pain and that pain intensity scores may not be the only reliable method of evaluating pain interventions or the quality of pain management. In support of this view, Gordon et al., (2010) proposed that pain interference should be a key component alongside pain intensity when evaluating postoperative pain. Furthermore, global impression of change in pain can also be applied in the clinical setting. The patient global impression of change scale can detect the effectiveness of pain interventions over time in contrast to pain intensity scores that pertain to specific points in time (O'Connor and Dworkin, 2011). In terms of pain research, this study challenges the primacy of pain intensity as an outcome as it demonstrated clinically meaningful improvements in pain management while pain intensity scores were not reduced as much by comparison.

Acute pain management has been dominated by the biomedical model with a focus on analgesics and invasive interventions such as intravenous opioids and local anaesthetic infusions. These methods have been shown to be effective in the immediate postoperative phase during which patients often remain in bed. For many patients, however, the following day results in severe pain which can limit mobility and affect recovery. This study has demonstrated that an integrated approach consisting of analgesics and supportive education can improve outcomes beyond the immediate postoperative period and reduce pain interference with maternal mobility. Moreover, outcomes affected by the intervention did not require increased doses of oxycodone. This supports the view that many other factors are associated with postoperative pain. Knowledge of these factors can be used to improve postoperative pain management.

Finally, the study showed that chronic postsurgical pain is a clinical issue that was associated with postnatal depression. This is an emerging public health issue as it undermines maternal health physically, psychologically, and socially (Recker and Perry, 2011). The finding that chronic pain was associated with postnatal depression adds evidence in support of new models of care. This suggests that the management of pain should begin prior to surgery and follow-up of patients be carried out in the months after surgery using appropriate assessment tools to identify chronic pain and maternal mental health problems. The clinical significance of this cannot be overstated because serious maternal disability may result from the experience (Lavand'homme, 2013).

6. Conclusions

The nurse practitioner intervention led to broad improvements to postoperative pain management and the trial results add new knowledge by demonstrating that acute pain management is not all about analgesics. This suggests that a new approach to pain management is required to manage the supplemental use of oral oxycodone with supportive strategies that include follow-up assessment and attention to the degree of participation desired by patients. The biopsychosocial approach to acute pain management is supported by the results of this research, clinical guidelines on acute pain management (Analgesic Expert Group, 2012), and national guidelines on the quality use of medicines (Australian Pharmaceutical Advisory Council, 2005). Despite these guidelines, little research has been conducted on integrated pain

Conclusioni

- Gli autori traggono le conclusioni del lavoro fatto
- Vengono sottolineati i dati rilevanti e i possibili sviluppi futuri
- Non devono essere in contrasto, nemmeno in parte, con i risultati

Conflitti d'interesse

- Gli autori devono dichiarare la presenza di finanziamenti da parte di aziende
- Possono essere di ordine economico ma anche di altro genere
- Considerare con cautela gli studi che hanno tra gli autori dipendenti di un'azienda farmaceutica o di dispositivi medico-sanitari
- Studi pubblicati in letteratura dimostrano che gli studi sponsorizzati raggiungono più spesso un risultato a favore del trattamento in esame.

Funding

This work was funded by the Italian Center of Excellence for Nursing Scholarship, Rome, Italy.

Conflict of Interest

No conflict of interest has been declared by the authors.

Trust, London, England (Dr Fellows).

Financial Disclosure: Mr Myklebust is an employee of Laerdal Medical Corp, which developed the monitor/defibrillator.

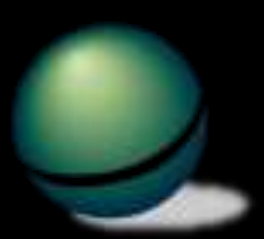
Corresponding Author: Lars Wik, MD, PhD, NAKOS, Institute for Experimental Medical Research, Ul-

Bibliografia

- Consente al lettore di risalire direttamente alle fonti citate dall'autore
- Permette di valutare se i riferimenti bibliografici sono aggiornati, pertinenti e corretti rispetto a quanto scritto dagli autori
- È bene diffidare dei lavori nei quali la bibliografia riporta molti articoli degli autori stessi (pericolosa autoreferenzialità)

La lettura critica
dell'articolo scientifico

Gli strumenti guida per la lettura critica



equator network

Enhancing the QUAlity and Transparency Of health Research

http://www.equator-network.org/

Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
Systematic reviews	PRISMA	Extensions
Study protocols	SPIRIT	PRISMA-P
Diagnostic/prognostic studies	STARD	TRIPOD
Case reports	CARE	Extensions
Clinical practice guidelines	AGREE	RIGHT
Qualitative research	SRQR	COREQ
Animal pre-clinical studies	ARRIVE	
Quality improvement studies	SQUIRE	
Economic evaluations	CHEERS	

- Arabic
- Chinese
- Dutch
- French
- German
- Greek
- Italian
- Japanese
- Korean
- Persian
- Polish
- Portuguese
- Russian
- Spanish
- Turkish
- Vietnamese

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

TABLE 1—The TREND Checklist (Version 1.0)

Paper Section/Topic	Item No.	Descriptor	Examples From HIV Behavioral Prevention Research
Title and abstract	1	• Information on how units were allocated to interventions • Structured abstract recommended • **Information on target population or study sample**	Example (title): A nonrandomized trial of a clinic-based HIV counseling intervention for African American female drug users
Introduction		• Scientific background and explanation of rationale	
Background	2	• **Theories used in designing behavioral interventions**	Example (theory used): the community-based AIDS intervention was based on social
Methods			
Participants	3	• Eligibility criteria for participants, **including crit** **levels in recruitment/sampling plan (e.g., cl** • Method of recruitment (e.g., referral, self-select **sampling method** if a systematic sampling pl • **Recruitment setting** • Settings and locations where the data were coll	
Interventions	4	• Details of the interventions intended for each st and when they were actually administered, s Content: what was given? Delivery method: how was the content given? **Unit of delivery: how were subjects grouped** Deliverer: who delivered the intervention? **Setting: where was the intervention delivere** Exposure quantity and duration: how many ses events were intended to be delivered? Ho intended to last? Time span: how long was it intended to take to to each unit? **Activities to increase compliance or adheren**	
Objectives	5	• Specific objectives and hypotheses	
Outcomes	6	• Clearly defined primary and secondary outcome • **Methods used to collect data** and any method the quality of measurements • Information on validated instruments such as p biometric properties	
Sample size	7	• How sample size was determined and, when ap of any interim analyses and stopping rules	
Assignment method	**8**	• **Unit of assignment (the unit being assigned t** **e.g., individual, group, community)** • **Method used to assign units to study conditio** **of any restriction (e.g., blocking, stratification, minimization)** • **Inclusion of aspects employed to help minimize potential bias** **induced due to nonrandomization (e.g., matching)**	alternate subjects enrolled (e.g., 2, 4, 6, etc.) were assigned to the comparison condition Example 2 (assignment method): for odd weeks (e.g. 1, 3, 5), subjects attending the clinic on Monday, Wednesday, and Friday were assigned to the intervention condition and those attending the clinic on Tuesday and Thursday were assigned to the comparison condition; this assignment was reversed for even weeks
Blinding (masking)	9	• Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding **was accomplished** and how it was assessed	Example (blinding): the staff member performing the assessments was not involved in implementing any aspect of the intervention and knew the participants only by their study identifier number
Unit of analysis	**10**	• **Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)** • **If the unit of analysis differs from the unit of assignment, the analytical**	Example 1 (unit of analysis): since groups of individuals were assigned to study conditions, the analyses were performed at the group level, where mixed effects models were used to account for random subject effects within each group Example 2 (unit of analysis): since analyses were performed at the individual level and communities were randomized, a prior estimate of the intraclass correlation coefficient was used to adjust the standard error estimates before calculating confidence intervals
Numbers analyzed	16	• Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible • Indication of whether the analysis strategy was "intention to treat" **or, if not, description of how noncompliers were treated in the analyses**	Example (number of participants included in the analysis): the analysis of condom use included only those who reported at the 6-month follow-up having had vaginal or anal sex in the past 3 months (75/125 for intervention group and 35/60 for standard group) Example ("intention to treat"): the primary analysis was intention to treat and included all subjects as assigned with available 9-month outcome data (125 of 176 assigned to the intervention and 110 of 164 assigned to the standard condition)
Outcomes and estimation	17	• For each primary and secondary outcome, a summary of results for each study condition, and the estimated effect size and a confidence interval to indicate the precision • Inclusion of null and negative findings • **Inclusion of results from testing prespecified causal pathways through which the intervention was intended to operate, if any**	
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are prespecified or exploratory	Example (ancillary analyses): although the study was not powered for this hypothesis, an exploratory analysis shows that the intervention effect was greater among women than among men (although not statistically significant)
Adverse events	19	• Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals)	Example (adverse events): police cracked down on prostitution, which drove the target population, commercial sex workers, to areas outside the recruitment/sampling area
Discussion			
Interpretation	20	• Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study • **Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations** • **Discussion of the success of and barriers to implementing the intervention, fidelity of implementation** • Discussion of research, **programmatic, or policy implications**	
Generalizability	21	• Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, **incentives, compliance rates, specific sites/settings involved in the study,** and other contextual issues	
Overall evidence	22	• General interpretation of the results in the context of current evidence and current theory	

Note. Masking (blinding) of participants or those administering the intervention may not be relevant or possible for many behavioral interventions. Theories used to design the interventions (see item 2) could also be reported as part of item 4. The comparison between study population at baseline and target population of interest (see item 14) could also be reported as part of item 21. Descriptors appearing in boldface are specifically added, modified, or further emphasized from the CONSORT statement. Boldface topic and descriptors are not included in the CONSORT statement but are relevant for behavioral interventions using nonrandomized experimental designs. The CONSORT statement[11] or the explanation document for the CONSORT statement[38] provides relevant examples for any topic or descriptor that is not in boldface. A structured format of the discussion is presented in *Annals of Internal Medicine* (information for authors; www.annals.org, accessed September 16, 2003).

Continued

Continued

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the inter view or focus group?	
Duration	21	What was the duration of the inter views or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.