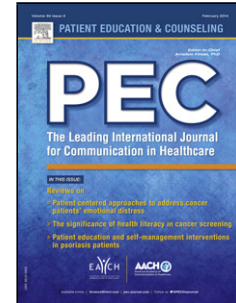# Accepted Manuscript

Title: Effectiveness of motivational interviewing to improve therapeutic adherence in patients over 65 years old with chronic diseases: A cluster randomized clinical trial in primary care

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- The most common intervention used by doctors is to prescribe drugs.
- Related to this is the problem of poor medication adherence.
- Motivational Interviewing, is an interview style designed to promote behavioural changes.
- Motivational Interviewing is a patient-centered methods that can be used to improve medication adherence en primary care.

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Effectiveness of motivational interviewing to improve therapeutic adherence in patients over 65 years old with chronic diseases: A cluster randomized clinical trial in primary care

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Abstract

Objective: To evaluate the effectiveness of motivational interviewing (MI) in improving medication adherence in older patients being treated by polypharmacy.

Methods: Cluster randomized clinical trial in 16 primary care centers with 27 health care providers and 154 patients. Thirty-two health care providers were assigned to an experimental (EG) or control group (CG). Interventions: MI training program and review of patient treatments. Providers in the EG carried out MI, whereas those in the CG used an "advice approach". Three follow-up visits were completed, at 15 days and at 3 and 6[0] months. Medication adherence in both groups was compared (p<0.05).

Results: Patients recruited: 70/84 (EG/CG). Mean age: 76 years; female: 68.8%. The proportion of subjects changing to adherence was 7.6% higher in the EG (p<0.001). Therapeutic adherence was higher for patients in the EG (OR=2.84), women (OR=0.24) and those with high educational levels (OR=3.93).

Conclusion: A face-to-face motivational approach in primary care helps elderly patients with chronic diseases who are being treated by polypharmacy to achieve an improved level of treatment adherence than traditional strategies of providing information and advice.

Practice Implications: MI is a patient-centered approach that can be used to improve medication adherence in primary care.

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1 Introduction

The most common intervention used by physicians is to prescribe medication.

However, a problem often related to this intervention is that of poor medication

adherence (MA). Medication adherence is defined as the patient's decision to accept

and follow the instructions for taking the prescribed medication [1,2]. In the setting of

chronic medical conditions such as hypertension and hypercholesterolemia, poor MA

leads to worse medical treatment outcomes, higher hospitalization rates, and

increased health care costs [3,4]. Because of this, adherence has been called "the key

mediator between medical practice and patient outcomes" [5].

In people over 65 years of age, the prevalence of polypharmacy has been estimated at

around 40% [6,7], and poor MA can have a negative health impact in this population

group. Therefore, this subpopulation is considered a target for optimization of MA

policies [8]. Different kinds of interventions have been tested to improve patient

adherence, ranging from simple adjustments in the medication regimen to complex

multidisciplinary interventions [9–13]. However, interventions to improve medication

compliance for chronic conditions appear to be less effective and a combination of

multifaceted interventions is considered the most effective strategy [14]. Given a lack

of confidence in the prescriber and treatment, and concerns surrounding patient

knowledge about prescribed medication [15], any strategy to improve medication

adherence must include clear and tailored information [15,16]. Furthermore, most

elderly patients frequently suffer from asymptomatic chronic diseases and many of

them do not consider medication necessary, which frequently leads them to stop

taking their medicine [17]. In these cases, communication strategies designed to

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promote patient self-empowerment and behavioral changes are particularly suitable [18].

Motivational Interviewing (MI) is an interview style designed to promote behavioral changes, and is defined as "a set of targeted communication skills to motivate patients to change their own behaviors in the interest of their health" [19]. In certain circumstances, MI has proven more effective than other strategies, such as the traditional informative strategy [20], and has been shown to be as equally effective as cognitive behavioral therapy, but with less time cost [21, 22]. However, evidence of the effectiveness of MI in these areas remains scarce and further studies are required [23, 24].

The objective of this study was to determine whether a face-to-face communicative strategy based on MI, used by health practitioners (family physicians and nurses) in a primary care setting and aimed at patients over 65 years old with a chronic disease who are being treated by polypharmacy and who have poor MA, can achieve better results than the usual approach based on an informative model of providing education and advice.

2 Methods

2.1 Study Design

This two-arm trial, with experimental group (EG) and control group (CG), was conducted using a cluster randomized design, where two subpopulation levels were considered: (1) health professionals and (2) patients. Figure 1 shows the CONSORT flow diagram with the cluster design features (25). The study took 18 months to

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complete, the patient recruitment period was from April 2009 to January 2010, and the follow-up period was 6 months.

2.2 Setting and Subjects

The study was conducted in 16 health centers in Córdoba Province, Spain. One hundred health care providers (nurses and physicians from our Department of Family Medicine mailing list) were invited to participate, and 32 accepted. Allocation was based on clusters, and was stratified by profession (nurse or physician). We performed blinded randomization to one of the two study arms (C4-Study Design Pack; Glaxo S.A.).

Patients older than 65 who had chronic disease and were being treated by polypharmacy (taking 5 or more medicines or 12 or more daily doses for a period of no less than 6 months) [26], and who had a high probability for non-adherence to the prescribed treatment, were selected (consecutive sample) by health care providers. An informed consent form was signed when each patient agreed to participate. Poor MA was assessed using the Haynes–Sackett [1] survey and the Morisky–Green test [27]. The former asks one question: "Most patients have difficulty taking all of their pills. Do you have any problems taking yours?" Because of its high specificity, this test is recommended in clinical practice as a first screening method to assess medication compliance [28]. The Morisky–Green scale comprises four yes/no questions: "Do you ever forget to take your medicines?"; "Are you careless at times about taking your medicine?"; "When you feel better, do you sometimes stop taking your medicine?"; and "Sometimes, if you feel worse when you take your medicine, do you stop taking it?" MA was considered to be poor when the patient answered affirmatively to the

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Haynes–Sackett question and answered inconsistently to at least one of the four

Morisky–Green test questions.

Patients who were excluded from the study were those with serious psychiatric and

neurological diseases, those who had difficulties coping with basic daily activities

(Barthel Index below 60) [29], those who had cognitive impairment (Pfeiffer's test)[30],

those admitted to hospital at least twice in the last year and patients under a carer's

supervision.

2.3 Interventions

Before intervention, health care providers in both groups attended a 15-hour

workshop on patient safety and MA. Then providers from the EG attended an

additional 20-hour-long workshop on MI. This training was conducted by two of the

authors (JAFG; JMPR), who are both family physicians with experience in teaching

physician-patient communication skills. The workshop was based on diverse

interactive methodologies (trigger videos, discussions, role-playing alternative

strategies, feedback and rehearsal).

To assess the effectiveness of specific training for acquisition of motivational skills,

participants in both groups were videotaped in a simulated encounter, and two

evaluators independently scored these interviews using the CICAA and EVEM tools.

The CICAA is a rating scale designed to evaluate patient-centered generic skills [31],

and the EVEM evaluates specific MI skills [32]. A previously published inter-rater

reliability assessment was carried out, which produced a good reproducibility index

(Cohen's kappa > 0.4 in all items, and intraclass correlation coefficient > 0.90). CICAA

scale results were as follows: rater A=30.57 points (EG) versus 16.56 points (CG),

p=0.003; rater B=29.7 (EG) versus 17.7 (CG), p=0.04. EVEM scale results were as

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follows: rater A=21.1 (EG) versus 12.1 (CG), p=0.022; rater B=20 (EG) versus 12.6 (CG), p=0.01.

Time between the training program and patient recruitment and intervention was about two weeks. Interventions in both groups included: 1) initial assessment of the status of each patient regarding medication; 2) detection of critical incidents and possible medication errors; 3) providing information (e.g., an informative pamphlet) that effectively describes prescribed medications (usefulness, indications, side effects, dosage, active formula, and other information) [33]; 4) developing a customized action plan; and 5) proposal for implementation of activities included in the plan. The latter two interventions were implemented using different approaches in each group: the CG based the interventions on informative, persuasive and advice strategies, while motivational strategies were used in the EG (see below).

2.4 Main Features of Motivational Interviewing

MI is a counselling method that involves enhancing a patient's motivation to change behavior by means of four guiding principles, represented by the acronym RULE: Resist the righting reflex; Understand the patient's own motivations; Listen with empathy; and Empower the patient. Conducting MI does not only involve applying a series of techniques, but also aims to create a spirit of collaboration and evoke a sense of personal resources, while respecting the patient's autonomy and personal freedom of choice [19].

Examination and resolution of ambivalence regarding treatment adherence is the main focus of this non-directive counselling, and the EG providers were trained to be intentionally directive in pursuing this goal. Intervention in the EG was more

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supportive than coercive and argumentative, with an overall goal to increase the patient's intrinsic motivation so that change could arise from within rather than being imposed from without. The EG providers followed these steps: 1) Assessment of ambivalence; 2) Exploration of patients' ideas and concerns about their lack of adherence; 3) Application of specific interviewing skills for re-framing and promoting self-efficacy (using empathy, developing discrepancies, avoiding arguments, confronting barriers and problems, supporting the patient, and others). The CG providers used an informative approach reinforced by persuasive strategies and personal advice.

2.5 Measurements and Outcomes

Scheduled visits were as follows: V0 or baseline visit (intake and initial assessment); V1 or second visit (at 15 to 20 days in patient's home); V2 or third visit (at 3 months in a health care setting); and V3 or final visit (at 6 months in patient's home). Office visits were about 15 minutes' duration, whereas home visits time were between 45 and 60 minutes, with no differences between the EG and CG.

Independent variables measured were: health center (urban or rural), provider (doctor or nurse), patient data (age, gender, marital status, educational level, occupation), chronic diseases, quality of life related to health, pharmacotherapeutic data, electronic prescription, treatment data (attendance at health center and hospital). Diseases were coded according to ICD-9 [34] classification, whereas drugs were classified by the ATC coding system [35]. Quality of life was measured by applying the COOP-WONCA charts [36].

Dependent variables measured were as follows. The primary outcome was MA, measured as average adherence percentage and calculated using the following

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formula: (Number of tablets presumably consumed/Number of tablets that should be consumed) × 100. An adherent patient was defined as having an average adherence >80% and <110% [1, 36, 37]. The method of MA assessment was similar at baseline and during the two follow-up home visits (V1 and V3), during which a review and medication count were taken.

2.6 Sample Size

This study belongs to a wider study, the ATEM-AP study, which has the additional aim of assessing the effect of MI in preventing medication errors [39]. Therefore, "medication errors" was another principal end-point variable and was used to calculate the sample size of the study. For a one-tailed test, an alpha error of 5% and a power of 80%, based on the results obtained by Fernandez-Lisón [40] (average medication errors per patient: 1.8 and 1 SD), we expect to find an average of 1.0 medication errors in the EG and 1.6 in the CG. For 1.0 SD and 15% losses, the minimum number of patients to be studied would be 46 per group. Estimates of the intracluster correlation coefficient in cluster randomized trials in primary care are generally less than 0.05 [40]. These intracluster correlation coefficients are translated to a cluster size of 15 on a design effect that corresponds to a factor of 1.7. Therefore, the predetermined sample size was 78 patients in each group (46 × 1.7 = 78, that is, 156 patients). Because the main outcome variable of the present study is MA, and considering our previous results [39], with this sample size a difference of 10% in MA between both groups could be detected (alpha error=5%, beta error=20%, unilateral hypothesis).

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2.7 Statistical Analysis

The Student's t-test and chi-squared test were used for analyzing differences between groups at baseline. McNemar's test was applied for assessing adherence. Absolute Risk Reduction (ARR = %MA in the EG – %MA in CG), Relative Risk Reduction (RRR = %MA in EG/%MA in CG) and Number Needed to Treat (NNT=1/ARR) were also calculated (95% confidence interval (CI)). To control for a cluster effect, a multilevel logistic regression was performed, considering the presence or absence of patient MA at the end of the study as a dependent variable. The independent variables in the maximum model were: group, profession, age, gender, marital status, educational level, social class, family situation, type of clinical care received in the last year, number of chronic health problems, quality of life, amount of medication, and electronic prescription use. The MLwiN software package (Centre for Multilevel Modelling, Bristol, UK) was used. The study was approved by the Clinical Research Ethics Committee of Reina Sofia Hospital in Córdoba, Spain.

3. Results

3.1 Baseline Characteristics

This study began with 154 patients (70 in the EG and 84 in CG) and ended with147 patients (66 in EG and 81 in CG) (Fig. 1). There were five losses (3/2 EG/CG) because they did not include any patient. There were 27 participating researchers (16 physicians and 11 nurses) in both groups: 11 males (4/7 EG/CG) and 16 females (8/8 EG/CG). None of the patients who were invited to participate refused to be included in the study.

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Average participant age was 76 years, and 68.8% were women. The two groups were comparable at baseline and there were no significant differences in any of the prognostic variables (Table 1). There was no significant difference between the groups regarding the number of medications taken at the first visit, medications stored at home, number of prescription or nonprescription medications, brand name or generic medication, and repeat or expired medication.

3.2 Proportional Change in Adherence Category

Figure 2 shows the percentage of patients classified as adherent in both groups at baseline and at the end of the study. The proportion of subjects changing to adherence in the EG was 24.3%, whereas it was 16.7% in the CG, i.e., 7.6% higher in the EG (McNemar's test; p<0.001).

3.3 Factors Related to Medication Adherence

Using multivariable analysis (Table 2) and after adjusting for other independent variables, those related to medication adherence were the following: motivational intervention (OR=2.57; 95% CI: 1.12–5.90), female patient (OR=0.16; 95% CI: 0.05–0.51), and high level of education (OR=5.68; 95% CI: 1.38–23.41). Other results were: ARR: 15.6% (95% CI: 1.0–32%), RRR: 1.54 (95% CI: 0.99–2.40), and NNT: 7 (95% CI: 4–20.6).

4. Discussion and Conclusion

4.1 Discussion

4.1.1 Main findings

In this study, MI showed a significant effect on improvement of MA in comparison with the usual intervention of providing patient information and advice. Providers who

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used a motivational strategy achieved an MA that was considered relevant to predetermined criteria (> 80% and <110%) and that was 7.6% higher than for providers those who did not use this strategy. Furthermore, MI was one of the three variables (together with being female and having a high educational level) that were independently associated with MA. The effectiveness of the intervention was not related to the type of provider.

4.1.2 Interpretation of findings and comparison with existing literature

In this study, both groups of participants, those undergoing MI intervention and those receiving more traditional intervention, significantly increased their adherence to treatment during the follow-up period. This result showed the efficacy of both interventions; however, MI helped patients to further improve treatment adherence and to achieve a level of adherence considered relevant from a clinical standpoint [1,37,38], compared with a communicative approach based on only offering advice and information. Traditional MI has been mainly used in the treatment of various lifestyle problems and diseases, psychological as well as physiological. In the field of behavioral change, controversy still exists about the usefulness of advice and education in contrast to more (intensive) patient-centered approaches such as MI [21,41]. The findings of this study provide evidence to support the usefulness of both approaches in promoting medication adherence in elderly patients who are being treated by polypharmacy. However, the study also shows the advantages of a motivational strategy over a traditional one, and adds to other previous studies in the area of adherence, using more carefully selected populations and health problems [42–44].

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In a primary care practice context, the practicability of any strategy is an important issue, and this is particularly true with respect to the application of MI counselling methods used to support the adherence efforts of patients taking medication [45]. This issue is closely related to other factors such as the provider, setting, timing of the intervention, and the number of sessions needed or duration of the effects. With respect to these practicability issues, our program characteristics (different providers, the number of visits, period between visits and duration of each visit) are in line with recommendations of the Spanish Primary Care Preventive Program (PAPPS) [47] and other Spanish regional health care programs [48]. Based on existing literature [41], one type of primary care practitioner (e.g., a physician) does not seem to be better equipped than another (e.g., a nurse) to provide face-to-face communication related to behavior change techniques. In our study, physicians and nurses were both trained in MI skills and delivered the intervention, providing evidence for the value of incorporating the MI communication style into clinical nursing practice, as other studies have also shown [44,48]. This is particularly important in a primary health care system, where the role of nurses is to a great extent, involved with the monitoring and follow-up of patients with chronic diseases. Thus, we consider the improvement in the main outcome as relevant not only because this kind of interventions are feasible in our setting (home visit programs) but also because they introduce a more respectful and patient-centered provider-patient relationship model. Although our motivational approach should be considered holistically, the role of some specific features stressed in our intervention can be highlighted here, particularly the specific evaluation of patient ambivalence and exploration of patient ideas and concerns about their lack of adherence, so as to apply specific interviewing skills. Carrying out any of these

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approaches specifically may be more feasible in a primary care context. Further research is needed to investigate the potential effect of these different interventions on MA in comparison with providing advice or information.

The percentage for participant lack of adherence recorded in this study was higher than that reported in other studies of polypharmacy in elderly patients. This low pattern of adherence at baseline could be owing to the fact that participants were chosen depending on their lack of adherence and the method used to identify this lack of adherence in the study (e.g., counting patients' pills). At the end of the period, participants in the EG increased their treatment adherence 24.3% whereas those in the CG increased 16.7%. Direct comparisons with other studies are difficult because of the varying time periods used to calculate adherence rates, the methods used to measure these rates and the type of patients and their health problems. Nevertheless, these figures can be considered comparable to those of other studies [44, 49]. Finally, the success probability of MI interventions increases with the number of patient encounters, and a longer follow-up period increases the percentage of studies showing a positive effect. Ruback et al. [21] found this effect in 36% of studies with 3 months of follow-up, whereas this effect was found in 81% of studies with a follow-up period of 12 months or more, for any type of intervention. Our study found interventions effective with a follow-up period of 6 months, so we can assume that our program could have produced even better adherence rates with a longer follow-up period.

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4.1.2 Strengths and limitations of the study

Our study has some limitations that should be noted. In line with what has been proposed by other authors (1,36,37), here we used a criterion of between 80% and 110% to define compliance as clinically significant. We consider this appropriate for the type of patients studied, the context of care in which the intervention was delivered and the characteristics of the intervention itself. However, it is certainly a subjective criterion, which may be considered inappropriate under different circumstances. This also represents a limitation in evaluating the real effectiveness of our intervention.

It was not possible to mask the intervention, either to patients or providers. This influences the performance and responsiveness of patients. Providers who chose to participate in the study may have had greater motivation for the study than those who declined. It is also possible that the CG providers conducted a more intensive intervention than usual (i.e., they might have been more friendly or pleasant with good performers and therefore more likely to improve patient compliance). Participants were recruited by consecutive sampling from among patients who had medical consultations for any reason, so we can assume that they were representative of the population that regularly attends primary care centers that also met the inclusion criteria. The multicentric nature of the study gives greater external validity to the results. Obviously, the study could not be blind. Furthermore, we assume observer bias (Hawthorne effect), implicit in the behavior they may adopt when they are invited to participate in a clinical trial. However this is not a differential bias here, since patients in both the experimental and control groups received an intervention

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On the other hand, some studies have shown that the very act of counting pills itself implies an increase in compliance that could mask any real effect. In any case, these factors could have produced a conservative effect on the results.

4.2 Conclusion

To promote adherence to treatments in elderly chronic patients who are being treated by polypharmacy, primary care physicians and nurses can effectively use both traditional informative and advice strategies and motivational approaches. Although MI seems to contribute more to acquiring levels of adherence considered relevant, more research is needed to establish the efficacy of this counselling approach.

4.3 Practice Implications

Motivational interviewing is a patient-centered method that can be used by physicians and nurses to improve medication adherence in primary care.

Figure Legends

Figure 1. CONSORT flow diagram
Figure 2. Percentage of adherence to medication (> 80% and <110%) in both groups at baseline and at the end of follow-up

Acknowledgments

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Conflict of interest

The authors have no conflict of interest to declare.

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Table 1. Study Population Baseline Characteristics

Variables	Intervention (n= 70)	Control (n= 84)	P value
Sociodemographics:			
-Age: Mean (SD)	75.6 (5.9)	76.1 (5.8)	0.712
-Gender: Number (%)			
Females	49 (70.0)	57 (67.9)	0.775
Males	21 (30.0)	27 (32.1)	
-Marital Status: Number (%)			
Marriage	44 (62.9)	50 (59.4)	
Widowed	21 (30.0)	30 (35.7)	0.413
Divorced	2 (2.9)	0 (0.0)	
Single	3 (4.3)	4 (4.8)	
-Education: Number (%)			
Illiterate	17 (24.3)	11 (13.1)	
No education	39 (55.7)	59 (70.2)	0.185
Primary Studies	11 (15.7)	12 (14.3)	
High School	3 (4.3)	1 (1.2)	
University Studies	0 (0.0)	1 (1.2)	
-Family Situation: Number (%)			
Living with children	9 (12.9)	16 (19.0)	
Couple	37 (52.9)	42 (50.0)	
Living with other relatives	4 (5.7)	1 (1.2)	0.533
Living alone (children nearby)	9 (12.9)	14 (16.7)	
Living alone (children far away/no kids)	7 (10.0)	6 (7.1)	
Couple with children	4 (5.7)	5 (6.0)	
Chronic Diseases: Mean (SD)	4.9 (2.1)	5.1 (2.6)	0.554
Self reported quality of life -COOP-WONCA Index-: Mean (SD)	27.4 (6.0)	28.8 (5.4)	0.122
Care Related and Medication:			
-Type of Visit (last year): Mean (SD)			
Health Centre Visits:	25.7 (19.0)	27.3 (19.8)	0.519
Home Visits:	2.1 (5.6)	2.1 (4.0)	0,918
-Electronic Prescription: Number (%)	65 (92.9)	75 (89.3)	0.443
-Medication consumption at the beginning of the study: Mean (SD)	8.7 (2.5)	9.0 (3.1)	0.576
-Medication Adherence at the beginning of the study: Mean % (SD)	86.05 (16.8)	80.9 (10.0)	0.053

SD: Standard Deviation

Table 2. Analysis of the variables related with Medication Adherence through Logistic regression analysis

Variables	OR	95% CI for OR	
		Lower	Upper
Group (EG vs. CG)	2.57	1.11	5.90
Gender (Male vs. Female)	0.16	0.05	0.50
Education (Yes vs. No)	5.67	1.37	23.41

EG: Experimental Group; CG: Control Group; OR: Odds Ratio; 95%CI: 95% Confidence Interval; Outcome (dependent variable): Medication adherence (yes vs. non). Independent variables considered in the model up and ruled out for lacking statistical significance: Provider (doctor vs. nurse), age, marital status, family situation (single vs. accompanied), electronic prescription, health centre visits, home visits, health chronics problems, amount of medication at the end of the study, medication adherence at baseline, self reported quality of life (COOP-WONCA). N=154; Hosmer & Lemeshow test=0.840.
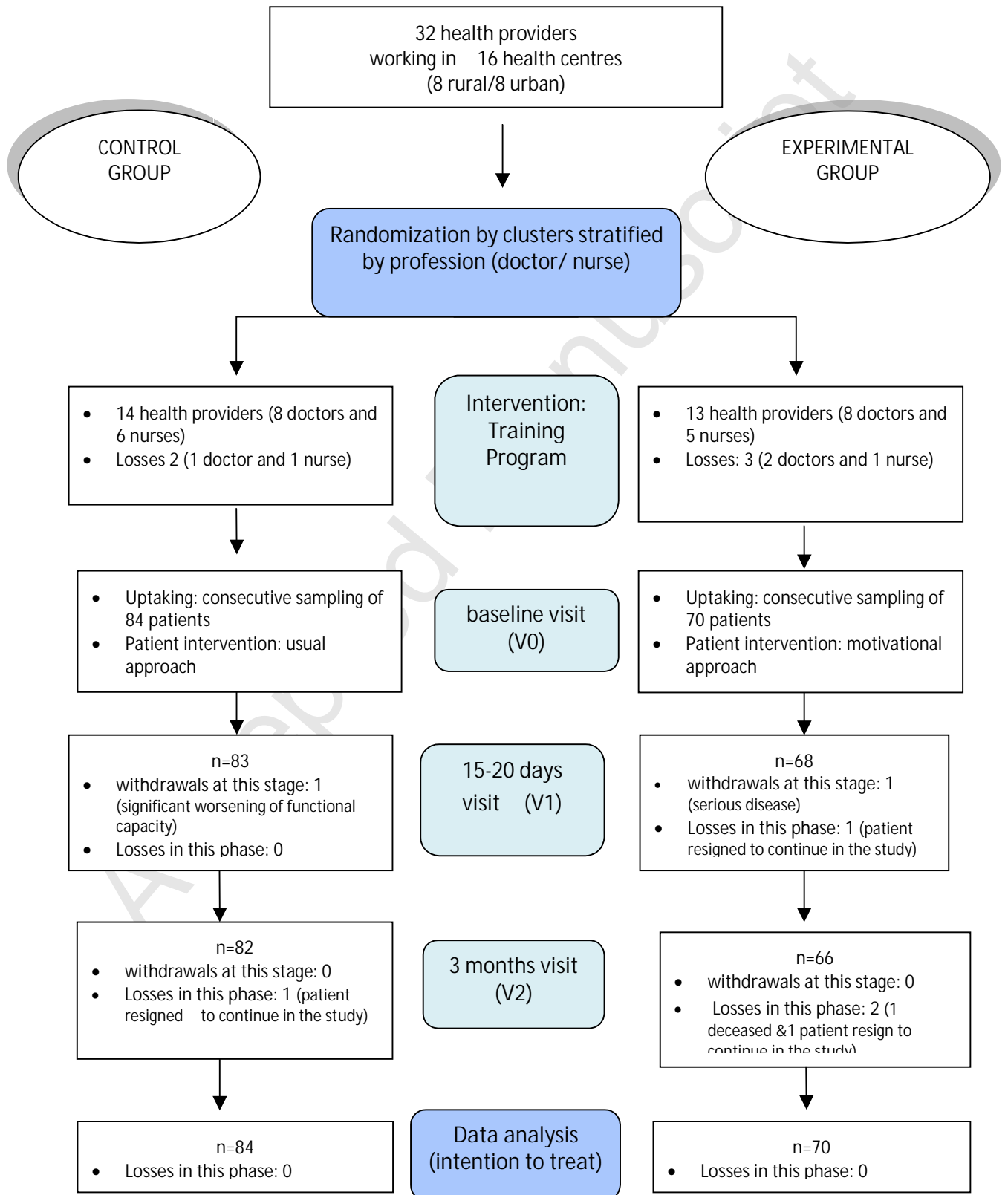
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Figure 1. Flow chart CONSORT

Figure 2. Medication adherence (>80% or <110%) in both groups at baseline and at final of follow-up