Computerized decision support to improve guideline implementation in cardiac rehabilitation: the CARDSS project

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Chapter 6

The effect of guideline-based computerised decision support on decision making of multidisciplinary teams: A cluster randomised trial in cardiac rehabilitation

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Abstract

Context: Multidisciplinary cardiac rehabilitation is critical to physical and psychosocial recovery and cardiovascular risk reduction in cardiac patients, but its provision is still insufficiently evidence-based in many Western countries. Computerised decision support is an effective instrument to improve guideline concordance of individual professionals. However, its effect in multidisciplinary settings is still unknown.

Objective: To determine the extent to which computerized decision support can improve multidisciplinary team concordance with guideline-recommended therapy decisions.

Design: Multi-centre cluster randomised trial.

Participants: Multidisciplinary cardiac rehabilitation teams in Dutch centres and their cardiac rehabilitation patients.

Interventions: Teams were randomised to receive an electronic patient record system with or without additional guideline-based decision support. Teams were enrolled between January and December 2005. All teams were required to electronically document their therapy decisions for all patients visiting the cardiac rehabilitation outpatient centre for at least six months.

Main outcome measures: Concordance with guideline recommendations was assessed for two standard rehabilitation therapies, exercise and education therapy, and for two new but evidence-based rehabilitation therapies, relaxation and lifestyle change therapy. Concordance data were analysed using generalised estimating equations to account for intra-cluster correlation, and were adjusted for patient age, sex, indication for cardiac rehabilitation, centre volume and type of centre.

Results: Data from 21 centres, including 2787 patients, were analysed. Computerised decision support increased concordance with guideline-recommended therapy decisions for exercise therapy by 7.9% (control 84.7%; adjusted difference 3.5% [95% CI: 0.1 to 5.2%]), for education therapy by 25.7% (control 63.9%; adjusted difference 23.7% [15.5 to 29.4%]), and for relaxation therapy by 25.5% (control 34.1%; adjusted difference 41.6% [25.2 to 51.3%]). The concordance for lifestyle change therapy increased by 3.2% (control 54.1%; adjusted difference 7.1% [-2.9 to 18.3%]). Computerised decision support reduced both cases of over- and under-treatment.

Conclusions: In a multidisciplinary team motivated to adopt a computerised decision support aid that assists in formulating guideline-based care plans, computerised decision support can be effective in improving multidisciplinary team's guideline concordance. Therefore, computerised decision support may also be considered to improve guideline implementation in such settings.
Introduction

One of the main challenges in contemporary healthcare is to increase the application of sound clinical evidence to routine care [1]. Although clinical practice guidelines are designed to promote effectiveness and discourage the use of ineffective treatments, guideline adherence in practice is often poor [1-3]. Dissemination of practice guidelines on paper alone has proven to be generally insufficient. Instead, a carefully designed change strategy usually needs to be deployed for effective guideline implementation [2;4-6].

Patient-tailored computerised decision support (CDS) to individual professionals at the point of care is one of the most effective methods to improve decision-making [1;4;5;7;8]. CDS has been shown to improve the decisions of individual professionals in cancer screening [9;10], vaccination [11], diabetes management [12;13], for (laboratory) test ordering [14;15], for drug dosing and prescribing [16;17], and in other settings [7]. However, CDS has also failed to improve practitioner performance [7;8;18;19], and it is unclear under which circumstances and settings it is optimally effective [7;20;21].

Specialist medical care is nowadays often provided not by individuals but by multidisciplinary teams [22-26]. Working in multidisciplinary teams integrates the professional knowledge and skills of different disciplines, and is generally considered to improve the coordination, quality, and continuity of patient care [22;24;25]. While individual decision making is mainly a cognitive process, decision making in teams is additionally influenced by the social context, such as the interpersonal relationships within the team [26;27]. It is unknown whether CDS can improve this process as all previous trials have evaluated the effect of CDS on the decisions of individuals.

This paper reports on a cluster randomised trial evaluating the effect of CDS on multidisciplinary team concordance with guideline-recommended therapy decisions in outpatient cardiac rehabilitation. Cardiac rehabilitation is a multidisciplinary secondary prevention strategy for patients who suffered a cardiac incident (e.g., a myocardial infarction) or underwent a cardiac intervention (e.g., heart surgery). Cardiac rehabilitation is critical to ensure that patients are in the best possible physical and psychosocial condition to return to and maintain their normal place in society, and to reduce their future cardiovascular risk [28-32]. Cardiac rehabilitation has proven to be cost-effective in economic evaluations conducted in North America and Europe [30]. However, in many Western countries cardiac rehabilitation practice is poorly standardised and does not follow the available scientific evidence [30;33;34]. The objective of this study was to determine the extent to which CDS can improve multidisciplinary team concordance with guideline-recommended therapy decisions.
Chapter 6. The CARDSS trial

To avoid contamination across patient groups due to teams learning from the system, a cluster randomised design was chosen [35]. As outpatient centres have only one multidisciplinary cardiac rehabilitation team, entire outpatient centres were the units of randomisation.

Methods

Guidelines for cardiac rehabilitation

To stimulate evidence-based cardiac rehabilitation services, the Netherlands Heart Foundation (NHF) and the Netherlands Society for Cardiology, patient interest and professional organisations respectively, published national guidelines for cardiac rehabilitation in 2004 [36]. Consistent with international standards [29;30;37], the national guidelines state that patients should be offered an individualised rehabilitation programme during which each of four therapies should be provided: two ‘standard’ therapies, namely exercise training and education therapy (education about the consequences of the patient’s disease), and two ‘new’ but evidence based therapies, namely lifestyle change therapy (risk-related behaviour adjustment), and relaxation and stress management training. To develop an individualised rehabilitation programme, the guidelines describe a needs assessment procedure which requires gathering of 15 to 40 data items concerning the patient’s medical, physical, psychological, and social condition and lifestyle. This procedure is generally conducted two weeks after discharge from the hospital after which, during weekly meetings, the multidisciplinary cardiac rehabilitation team decides upon the content of the patients’ rehabilitation programme based upon the information collected during the needs assessment procedure. The team, which usually includes physical therapists, nurses, psychologists, dieticians, social workers, and rehabilitation specialists or cardiologists, is jointly responsible for execution of this programme during the next six to twelve weeks. All outpatient cardiac rehabilitation services act under the responsibility of cardiologists.

The CARDSS guideline implementation system

To stimulate the implementation of these guidelines, an electronic patient record system with CDS functionalities named CARDSS (Cardiac Rehabilitation Decision Support System) was developed [38]. CARDSS actively guides users through the needs assessment procedure via a structured dialogue, prompting them to record the necessary information. In addition, CARDSS assists in formulating a patient-specific rehabilitation programme by providing computerised decision support: it automatically shows whether each of the four therapies is recommended by the
guidelines, based on the patient’s needs assessment data. Upon request, CARDSS provides the rationale behind its recommendations and links to relevant research evidence.

During the trial, the collection of the patient’s needs assessment data was done by one or more members of the multidisciplinary cardiac rehabilitation team, usually a specialised nurse or therapist, during a 30 to 60 minute meeting with the patient. These members of the cardiac rehabilitation team recorded this patient data directly into CARDSS during the visit, or entered the data into CARDSS shortly afterwards. The data was subsequently used as input for the weekly multidisciplinary team meeting where all decisions regarding the patient’s rehabilitation programme were made. The needs assessment data recorded in CARDSS, including its guideline-based therapy recommendations from the system, were always available during this meeting, either directly through CARDSS (e.g. projected on a screen), or on a paper report printed with CARDSS. The final therapy decisions of the team were recorded in CARDSS at the end of the meeting.

To facilitate user acceptance, CARDSS provided additional patient information management services, including registration, documentation, and calculation of summary statistics across patients [38,39]. In a pilot study in four cardiac rehabilitation centres, CARDSS was readily accepted and integrated into existing working procedures [40].

Participants
The national guidelines and CARDSS were jointly presented at a national conference on cardiac rehabilitation in January 2004. Six months later, the NHF surveyed all 101 Dutch cardiac rehabilitation centres for their interest in purchasing the system for €100 (approx. £83 UK, $130 US). Each interested centre was eligible to participate in the trial, except for the four centres that participated in the pilot study [40]. Participation required that the centre agreed to document the needs assessment of each cardiac rehabilitation patient seen during the trial in CARDSS. Trial participants were offered several incentives including reimbursement of CARDSS purchasing costs, free training, and free helpdesk services.

Intervention
Participating centres worked with either of two versions of CARDSS: an intervention version or a control version. The intervention version had full functionality, while the control version comprised all patient information management services but did not provide therapy recommendations. This way we controlled for the potential positive
effect of the information management services and dialogue structure provided by CARDSS on the decision making of rehabilitation professionals, a phenomenon known as the ‘checklist effect’ [41;42]. In the control arm, multidisciplinary teams selected rehabilitation therapies using their own judgment; the written guidelines could always be consulted on paper or electronically within CARDSS. Control arm teams could explain their decisions, but were not obliged to do so. Intervention arm teams could base their decisions on the system’s therapy recommendations. Non-concordance with guideline recommendations required recording of the reason, such as ‘patient refusal’, ‘lack of facilities’, ‘disagreement with guideline’, and ‘other’.

At the start of the centre’s inclusion in the study, all multidisciplinary cardiac rehabilitation teams received a standardised training course, designed by the investigators, during which both the control and intervention versions of CARDSS were demonstrated to all teams. Teams participated in the study for at least six months, after which they all received the full version of CARDSS.

An external evaluator with extensive experience in evaluation of information technology in healthcare was consulted (JW) during the design of the study protocol and the intervention.

According to the medical ethics committee of the Academic Medical Centre in Amsterdam, the study required no formal approval.

**Outcome measures**

For all four cardiac rehabilitation therapies individually, concordance of the multidisciplinary team therapy decisions with the guidelines was used as the outcome measure. Concordance was defined at patient level and implied treating patients who should have been treated and not treating patients who should have been untreated, according to the guideline. To evaluate the effect of CDS on multidisciplinary team decision making, the proportions of concordant cases between the intervention and control arms were compared. In addition, we evaluated the effect of the CDS on undertreatment (withholding treatment from patients who should receive it) and overtreatment (treatment of patients who should be left untreated) of patients.

**Sample size**

Based on data from the pilot study [40], a mean of 22 eligible patients per month per centre and an average intra-cluster correlation coefficient (ICC) of 0.04 and average baseline concordance rate of 60% for all four cardiac rehabilitation therapies were used as estimators in the sample size calculation. Calculations showed that using a six-month follow-up would require 36 participating centres to detect a 10% absolute
difference in guideline concordance rate with 80% power at a Type I error risk (alpha) of 5%. Sample size [43] was calculated using the STATA statistical software package (Stata Corporation, College Station TX, USA).

Randomisation and Allocation
Concealed randomisation using variable block sizes was performed using dedicated software, stratified by type of centre (university hospital; autonomous rehabilitation centre, and non-university hospital). Non-university hospitals were also stratified by the mean number of new patients seen per month in the year prior to randomisation (less than 20; 20 to 30; more than 30).

After the standardised training course had been given by the project team, the centre in question received an email message with a key code that activated CARDSS and determined team allocation to control or intervention arm. Allocation could not be influenced by, and was unknown to, the investigator giving the course. Centres could not be blinded to allocation due to the character of the intervention.

Data validation
During the trial, all centres were asked to retain their original administration system (mostly the paper-based patient record) to record information on patients’ rehabilitation programmes.

To assess the quality and completeness of record keeping in CARDSS, a data audit was conducted in each participating centre during or at the end of the trial. During the data audit, the records of ten cardiac rehabilitation patients created during the trial period were randomly selected from the centre’s original administration system which served as a reference standard. First, to verify that all cardiac rehabilitation patients seen at participating centres had been entered into CARDSS, we checked if each of the selected patients had a record in CARDSS. Second, the quality of patient data stored in CARDSS was verified by comparing each of the ten patients’ demographic information and therapy decisions recorded in the original administration system with the data in CARDSS.

If two or more selected patients were not found in CARDSS or if discrepancies in demographic information or therapy decisions existed in more than two records, all data of the centre in question were considered unreliable and were excluded from the analyses. If a centre passed the data audit, but data analysis showed that twenty percent or more of a centre’s patient records missed any data necessary to determine guideline concordance, that centre was excluded from the analyses.
To reduce potential dilution of the treatment contrast by centres’ potential suboptimal performance in the initial phase (learning curve before reaching a plateau), the data of patients enrolled in the first two weeks of using CARDSS in each participating centre, with a minimum of ten patients, were excluded from the analyses. The outcome assessment was performed unblinded, but could not be influenced by the assessors as concordance data were not subject to judgement.

**Statistical analysis**

The effects of CDS on guideline concordance were estimated at the patient level, by fitting logistic regression models to the concordance data for the four types of therapy. Three patient-level variables (age, sex, and indication for cardiac rehabilitation) and two centre-level variables (weekly volume of new patients, and whether or not the centre is either a specialised rehabilitation centre or part of an academic hospital) were used as covariates to adjust for differences in case-mix between intervention and control group. Natural splines were used to model nonlinear effects of continuous variables (age and centre volume). Furthermore, to account for potential correlation of outcomes within centres, we used generalised estimation equations with exchangeable correlation [44;45]. Because of the small number of clusters, the analyses were repeated with jackknife estimators of variance [46;47]. In addition, the analysis described above was repeated to estimate the effect of CDS on undertreatment and overtreatment of patients. The statistical analyses were performed with SPLUS version 6.2 (Insightful Corp, Seattle, WA, USA).

**Results**

In October 2004, 40 centres who were interested in purchasing CARDSS were invited to participate in the trial. Thirty-five centres (88%) accepted this invitation. Of these, four centres were unable to implement the system before the end of the recruitment period because of inadequate ICT infrastructure. Figure 1 shows that the remaining 31 centres were assigned to the intervention arm (16 centres) or the control arm (15 centres). Centres were enrolled in the trial between January and December 2005. The last centre completed participation in the trial in July 2006.

database during an update of the server’s operating system in the last month of the trial.
The data audit revealed poor data quality in three intervention centres which were therefore excluded from the analysis; in these centres, participants reported that they were unaware that they had to record their therapy decisions in CARDSS after consulting its recommendations. Data from a further one intervention and one control centre were excluded as in both centres more than 70% of patient records missed one or more data items due to inappropriate system use. Data from 21 centres including 2787 patients were analysed. Table 1 lists the baseline characteristics of both trial arms at the level of centres and patients.

During the trial, five control arm centres discontinued their participation: Three control centres were reluctant to continue participation as they believed that the benefits of CARDSS without CDS did not compensate for the increased workload of learning to work with the system. One control centre had to stop participation due to a temporary lack of personnel and another centre accidentally deleted its CARDSS

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**Figure 1. Flow of centres through the trial.**

CR: Cardiac rehabilitation, NL: the Netherlands, CDS: computerised decision support

<table>
<thead>
<tr>
<th>Total CR clinics in NL (101 clinics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total CARDSS buyers (44 clinics)</td>
</tr>
<tr>
<td>- Pilot study participants (4 clinics)</td>
</tr>
<tr>
<td>- Refused to participate (5 clinics)</td>
</tr>
<tr>
<td>- Unable to start in recruitment period (4 clinics)</td>
</tr>
</tbody>
</table>

**Randomized (31 clinics)**

<table>
<thead>
<tr>
<th>Allocated to intervention (16 clinics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discontinued participation (1 clinic)</td>
</tr>
<tr>
<td>- Lack of personnel (1 clinic)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Allocated to control (15 clinics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discontinued participation (4 clinics)</td>
</tr>
<tr>
<td>- Lack of motivation (3 clinics)</td>
</tr>
<tr>
<td>- Lack of personnel (1 clinic)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Trial Completed (15 clinics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analyzed: 12 clinics; 1655 patients mean # patients = 138, range 42-322</td>
</tr>
<tr>
<td>Excluded: 3 clinics (48, 49, and 67 patients)</td>
</tr>
<tr>
<td>Reasons: Did not pass audit (3 clinics)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Trial Completed (11 clinics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analyzed: 9 clinics; 1132 patients mean # patients = 126, range 27-251</td>
</tr>
<tr>
<td>Excluded: 2 clinics (85 and unknown # of patients)</td>
</tr>
<tr>
<td>Reasons: Too much missing data (1 clinic)</td>
</tr>
<tr>
<td>Accidentally deleted database (1 clinic)</td>
</tr>
</tbody>
</table>
### Table 1. Baseline characteristics of clusters and patients

<table>
<thead>
<tr>
<th>Centre-level variable</th>
<th>Centres analysed</th>
<th>Centres excluded or lost to follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Interv. arm (n=12)</td>
<td>Control arm (n=9)</td>
</tr>
<tr>
<td>Number of patients (median [IQR])</td>
<td>113 [85 to 150]</td>
<td>126 [78 to 171]</td>
</tr>
<tr>
<td>Trial period in months (median [IQR])</td>
<td>7.4 [6.8 to 8.1]</td>
<td>8.1 [6.9 to 8.6]</td>
</tr>
<tr>
<td>Number of patients per month (median [IQR])</td>
<td>14 [13 to 19]</td>
<td>15 [14 to 19]</td>
</tr>
<tr>
<td>Stratum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Medium</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Large</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Rehabilitation centres</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>University centres</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Patient-level variables (n=1655)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years) ± SD</td>
<td>60.6 ± 11.5</td>
<td>61.0 ± 11.3</td>
</tr>
<tr>
<td>Male sex (%)</td>
<td>1198 (72%)</td>
<td>862 (76%)</td>
</tr>
<tr>
<td>Indication for cardiac rehabilitation +</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart surgery (%)</td>
<td>633 (38.2%)</td>
<td>471 (41.6%)</td>
</tr>
<tr>
<td>ACS (%)</td>
<td>678 (41.0%)</td>
<td>408 (36.0%)</td>
</tr>
<tr>
<td>AP or PCI (%)</td>
<td>281 (17.0%)</td>
<td>173 (15.3%)</td>
</tr>
<tr>
<td>Other (%)</td>
<td>63 (3.8%)</td>
<td>80 (7.1%)</td>
</tr>
</tbody>
</table>

IQR: interquartile range
ppm: patients per month
SD: standard deviation

*: This information is based on only the data of one control arm centre that was excluded from the final analyses due to too much missing data. This information is not available for the five control arms centres that dropped out during the trial as they stopped registering their needs assessment data electronically.

+ The ‘Heart surgery’ group includes patients with a coronary artery bypass (CABG) surgery, and patients with a valvular surgery. The ‘ACS’ (Acute Coronary Syndrome) group includes patients with a myocardial infarction or instable AP (angina pectoris) with or without a PCI (Percutaneous Coronary Intervention). The ‘AP or PCI’ group includes patient with AP with or without a PCI. The ‘Other’ category includes ICD (Internal Cardio Defibrillator) patients, heart failure patients, patient with congenital heart disease, and patient that received cardiac rehabilitation based on another cardiac disease.
Table 2. Primary results of the trial. The table shows concordance rates and the difference in concordance with guideline recommendations for the four measured rehabilitation therapies between intervention and control group.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention</th>
<th>Control</th>
<th>Crude difference</th>
<th>Adjusted difference [95% CI]</th>
<th>ICC</th>
<th>NA (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nr of centres</td>
<td>12</td>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nr of patients</td>
<td>1655</td>
<td>1132</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concordance with guideline recommendations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise (#)</td>
<td>92.6% (1508)</td>
<td>84.7% (933)</td>
<td>7.9%</td>
<td>3.5% [0.1 to 5.2]</td>
<td>0.086</td>
<td>56 (2.1)</td>
</tr>
<tr>
<td>Education (#)</td>
<td>87.6% (1411)</td>
<td>63.9% (709)</td>
<td>25.7%</td>
<td>23.7% [15.5 to 29.4]</td>
<td>0.187</td>
<td>67 (2.4)</td>
</tr>
<tr>
<td>Relaxation (#)</td>
<td>59.6% (959)</td>
<td>34.1% (373)</td>
<td>25.5%</td>
<td>41.6% [25.2 to 51.3]</td>
<td>0.479</td>
<td>83 (3.0)</td>
</tr>
<tr>
<td>Lifestyle change (#)</td>
<td>57.4% (924)</td>
<td>54.1% (601)</td>
<td>3.2%</td>
<td>7.1% [-2.9 to 18.3]</td>
<td>0.110</td>
<td>67 (2.4)</td>
</tr>
</tbody>
</table>

NA: Data not available.

+ Adjusted for age, sex, and diagnosis at the patient-level, and weekly volume of new patients and whether or not the centre is either a specialised rehabilitation centre or part of an academic hospital at the centre-level.

Figure 2. Concordance of the control and intervention centres with the guideline-recommended therapy decisions for the different therapies. Each box shows median value (line inside box), quartiles (box edges), extreme values (whiskers), and outliers (horizontal lines) within a category.
Table 2 shows the primary results of the trial. CDS increased concordance with guideline recommendations for the exercise, education, and relaxation therapy. The increased concordance with therapy decisions for the lifestyle change therapy was not statistically significant. Table 2 only reports the confidence intervals according to the standard GEE estimator as similar results were found with the jackknife estimator. The jackknife estimator did result in borderline significance for the exercise therapy (95% CI: 0.0 to 5.4%).

For all four therapies the actual ICC was higher than anticipated, especially for education and relaxation therapy. Guideline concordance in the control group for the exercise therapy was higher than had been estimated in the sample size calculation, but was much lower than estimated for the relaxation and lifestyle change therapy. Figure 2 shows the variation in concordance with guideline recommendations for each therapy.

### Table 3. The number and percentage of patients that were correctly treated (true positives), correctly untreated (true negatives), overtreated (false positives), and undertreated (false negatives) for each individual cardiac rehabilitation therapy (3.1 to 3.4), separately for the intervention and control centres.

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Intervention Arm</th>
<th>Control Arm</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exercise</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Received Yes</td>
<td>1356 (83.2%)</td>
<td>853 (77.4%)</td>
</tr>
<tr>
<td>Received No</td>
<td>79 (4.8%)</td>
<td>100 (9.1%)</td>
</tr>
<tr>
<td>Total</td>
<td>1435 (88.1%)</td>
<td>953 (86.5%)</td>
</tr>
<tr>
<td><strong>Relaxation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Received Yes</td>
<td>1278 (79.4%)</td>
<td>676 (61.8%)</td>
</tr>
<tr>
<td>Received No</td>
<td>156 (9.7%)</td>
<td>334 (30.1%)</td>
</tr>
<tr>
<td>Total</td>
<td>1434 (89.1%)</td>
<td>985 (88.7%)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Received Yes</td>
<td>248 (15.4%)</td>
<td>160 (14.4%)</td>
</tr>
<tr>
<td>Received No</td>
<td>672 (41.7%)</td>
<td>458 (41.3%)</td>
</tr>
<tr>
<td>Total</td>
<td>920 (57.1%)</td>
<td>618 (55.7%)</td>
</tr>
<tr>
<td><strong>Lifestyle</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Received Yes</td>
<td>1356 (83.2%)</td>
<td>853 (77.4%)</td>
</tr>
<tr>
<td>Received No</td>
<td>79 (4.8%)</td>
<td>100 (9.1%)</td>
</tr>
<tr>
<td>Total</td>
<td>1435 (88.1%)</td>
<td>953 (86.5%)</td>
</tr>
</tbody>
</table>

Table 3.1a. Exercise therapy, intervention arm

Table 3.1b. Exercise therapy, control arm

Table 3.2a. Relaxation therapy, intervention arm

Table 3.2b. Relaxation therapy, control arm

Table 3.3a. Education therapy, intervention arm

Table 3.3b. Education therapy, control arm

Table 3.4a. Lifestyle change therapy, intervention arm

Table 3.4b. Lifestyle change therapy, control arm
Table 3 shows the crude data on guideline recommendations and multidisciplinary teams’ therapy decisions for both study arms and for each of the four therapies. In both the intervention and control arm, undertreatment was more common than overtreatment, in particular for the relaxation, education, and lifestyle change therapies, with significant differences between the two study arms form the relaxation and education therapies. These therapies should have been given to 2310 (84.6% of all patients) and 2419 (88.6%) patients respectively, of which 1310 (56.7%) and 490 (20.3%) did not receive the recommended therapy. The adjusted difference between the control and intervention arm in undertreatment was 42.8% [1.1% to 68.0%] and 25.8% [14.9% - 33.6%] respectively, in favour of the intervention arm. A significant difference was also found for exercise therapy overtreatment. From the 343 patients (12.2% of all patients) who should not have been given exercise therapy, 111 patients (32.4%) did incorrectly receive this treatment. The adjusted difference in exercise therapy overtreatment between the two study arms was 25.7% [4.3% to 54.1%]. Other differences between the study arms were either not statistically significant or very small.

In the intervention arm, patient refusal was reported as the main reason for non-concordance with recommendations for exercise (77/121), education (127/199), relaxation (407/651), and lifestyle change therapies (381/686). Lack of sufficient facilities was another important reason for non-concordance with recommendations about lifestyle change (160/686) and relaxation therapy (68/651). In the control arm, recording of non-concordance was voluntary which resulted in reasons being recorded in only 152 (8%) of the 1821 non-concordant decisions. For those decisions, patient refusal was also the main reason for non-concordance with recommendations for all four therapies.

**Discussion**

**Statement of principal findings**

We found that computerised decision support improved the concordance of multidisciplinary cardiac rehabilitation teams’ decisions for three out of four rehabilitation therapies for which concordance with guideline recommendations was measured. CDS reduced both cases of over- and undertreatment.

**Strengths and weaknesses of the study**

Although recruiting participants for trials is always difficult, the recruitment for a CDS trial faces some additional challenges. In this study, entire multidisciplinary teams had to be recruited instead of individual professionals or patients, requiring not just one
professional but the entire team to be motivated to participate. In addition, motivated teams could only participate if i) their centre had an adequate IT infrastructure and ii) both the team and the centre’s IT department were willing and able to allocate resources for implementation of CARDSS within a limited time frame. For this reason only 31 of the 101 eligible centres were enrolled in the study, which is nevertheless among the largest numbers of participants in CDS evaluation studies to date [7]. It does restrict the generalizability of our results to settings where teams are motivated to work with a CDS aid and where sufficient IT support and facilities are available to implement the CDS system. However, as IT support and facilities are rapidly improving in most hospitals we believe that this requirement will be less of concern for such trials in the future.

Another potential source of bias in our results is the attrition rate. In the control arm, three centres discontinued participation as they found that it was not worth the effort implementing CARDSS in their daily practice without receiving decision support. In the intervention arm, three clinics were excluded from the analyses as they failed to properly record therapy decisions in CARDSS. Such dropouts make it impossible to perform a genuine intention-to-treat analysis. However, attrition did not seem to be related to guideline concordance, but to the fact that teams faced the additional barrier of implementing a new electronic patient record system, as well as learning to use the CDS aid. Therefore we believe that if CDS can be provided via an electronic patient record system that is already used on a routine basis, the additional benefit of CDS will be more easily realised.

In the intervention group, multidisciplinary teams were prompted to record the reason for non-concordance when they did not follow a recommendation of the system. This necessity to record the reason for non-concordance may have pressured the teams to follow the recommendations, thus increasing concordance with the guideline. Although we believe it is unlikely that entire teams let their decisions be affected by the necessity to motivate non-concordance, the effect size of this CDS feature is unknown.

In our study the research team also led the development of the CDS system. Garg et al. [7] found that this can lead to a potential bias in outcome assessment. However, a number of factors should have reduced the chances of such biases, including blinding of the investigators during the allocation procedure, objective outcome measures, and the involvement of an external evaluator (JW) and a statistician (GtR) from another department outside the project team.

In this study we measured the impact of CDS on concordance with guideline recommended therapy decisions by teams, which is a measure of care process quality. When evaluating the effect of quality improvement interventions it is common to use
such process measures instead of patient outcomes [7]. Process measures are even preferable over patient outcomes if the process measures are based on evidence or accepted standards of care[7;48], as is the case in cardiac rehabilitation [36].

**Strengths and weaknesses in relation to other studies**

Many studies have previously studied the effect of CDS on individual professional decision making. Two systematic reviews found that active CDS systems, i.e. systems that automatically provide individual professionals with advice, are more effective than passive systems, which require professionals to request advice [7;20]. Therapy recommendations rather than diagnostic advice and CDS at the time and location of decision making were also found to increase CDS’ chances of success. These known success factors of CDS systems were taken into account during the development of CARDSS [38] and were judged favourably by its users in a usability study [49]. The positive opinion of professionals towards CARDSS is also reflected by the fact that it is still used in over 35 of the 101 outpatient centres in the Netherlands.

A cluster randomised trial is usually the most rigorous method to evaluate interventions intended to affect professionals’ behaviour [50-52]. So far, however, only a few CDS evaluation studies have applied the cluster randomised design, and even fewer studies accounted for the clustering of patients in the statistical analysis [53]. Our study design ensured that the estimated effects of CDS could not be biased by the ‘checklist’ [41;42], ‘Hawthorne’, ‘feedback’, or ‘carryover effects’ described by Friedman and Wyatt [35] and our statistical analysis accounted for correlation of concordance measurements within centres [54].

**Meaning of the study**

Although multidisciplinary settings are common in contemporary healthcare, no studies have yet evaluated the effect of computerised decision support in such a setting [7]. In contrast to decision making by individual professionals, multidisciplinary decision making depends on social factors, such as the experience, profession, interpersonal relationships, and characters of team members [24-27]. Our results show that CDS can also be an effective instrument in multidisciplinary setting where such social factors play an important role in decision making.

This study shows that, in a multidisciplinary team motivated to adopt a computerised decision support aid that assists in formulating guideline-based care plans, computerised decision support can be effective in improving multidisciplinary team’s guideline concordance. Based on our findings, we encourage the use of CDS aids in settings where multidisciplinary teams are motivated to use them.
Unanswered questions and future research

CDS did not improve guideline concordance for the lifestyle change therapy, and although guideline concordance for the relaxation therapy increased, there still existed considerable undertreatment. Although centres started to participate in the trial between one and two years after the release of the guideline in which these therapies were officially introduced, a considerable number of outpatient clinics still had insufficient facilities to offer these ‘new’ therapies to all eligible patients during the trial. The literature emphasises that many different types of barriers to guideline implementation exist which may require different change strategies [2;4;5], but little is known about the types of barriers that different change strategies, including CDS, can address [4;5]. Our results suggest that a CDS system alone is insufficient to improve guideline concordance when this requires additional resources, for example in increasing uptake of lifestyle change therapy. More research is therefore needed to understand how CDS improve guideline concordance and which additional change strategies need to be considered to overcome the remaining barriers.

Reference List


Chapter 6. The CARDSS trial


