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Comparative effectiveness of diabetes self-management education programs

Jürgen M. Pelikan, Sandra Peer, Kristin Ganahl, Lukas Baumann
(LBIHPR)

Stephan van der Broucke, Louise Schinckus, Jessica van den Bosch
(CU Louvain)

Kristine Sorensen, Timo Clemens
(U Maastricht)

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LBIHPR: A-1020 Vienna, Untere Donaustraße 47, Austria | office@lbihr.lbg.ac.at | www.lbihr.lbg.ac.at | +43 1 2121493 -10 | FAX - 50

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1. BACKGROUND AND OBJECTIVES OF THE STUDY

Background

- There is evidence that diabetes self-management (DSM) interventions have beneficial effects on patients. (e.g. Huxley, et al. 2015, Schillinger, D. et. Al. 2009; Ellis et al., 2004; Deakin, et al. 2005 ; Mensing, CR., Norris, SL, 2003; Norris, et al. 2001;)
- There are also studies comparing two selected communication channels with each other, but no studies comparing more than two communication channels. (Pillay, et al. 2015; Sperl-Hillen, et al. 2011;)
- Therefore a comparative, observational, pre-post, multi-center & multi-national effectiveness study of DSM programs using five different communication channels was included in the FP7 Diabetes Literacy Project, funded by EU and nationally.
 - A study on impact of communication channels and role of health literacy
 - A study on impact of program implementation fidelity on effectiveness of programs
 - A study on organizational effectiveness of programs

Objectives of the Studies

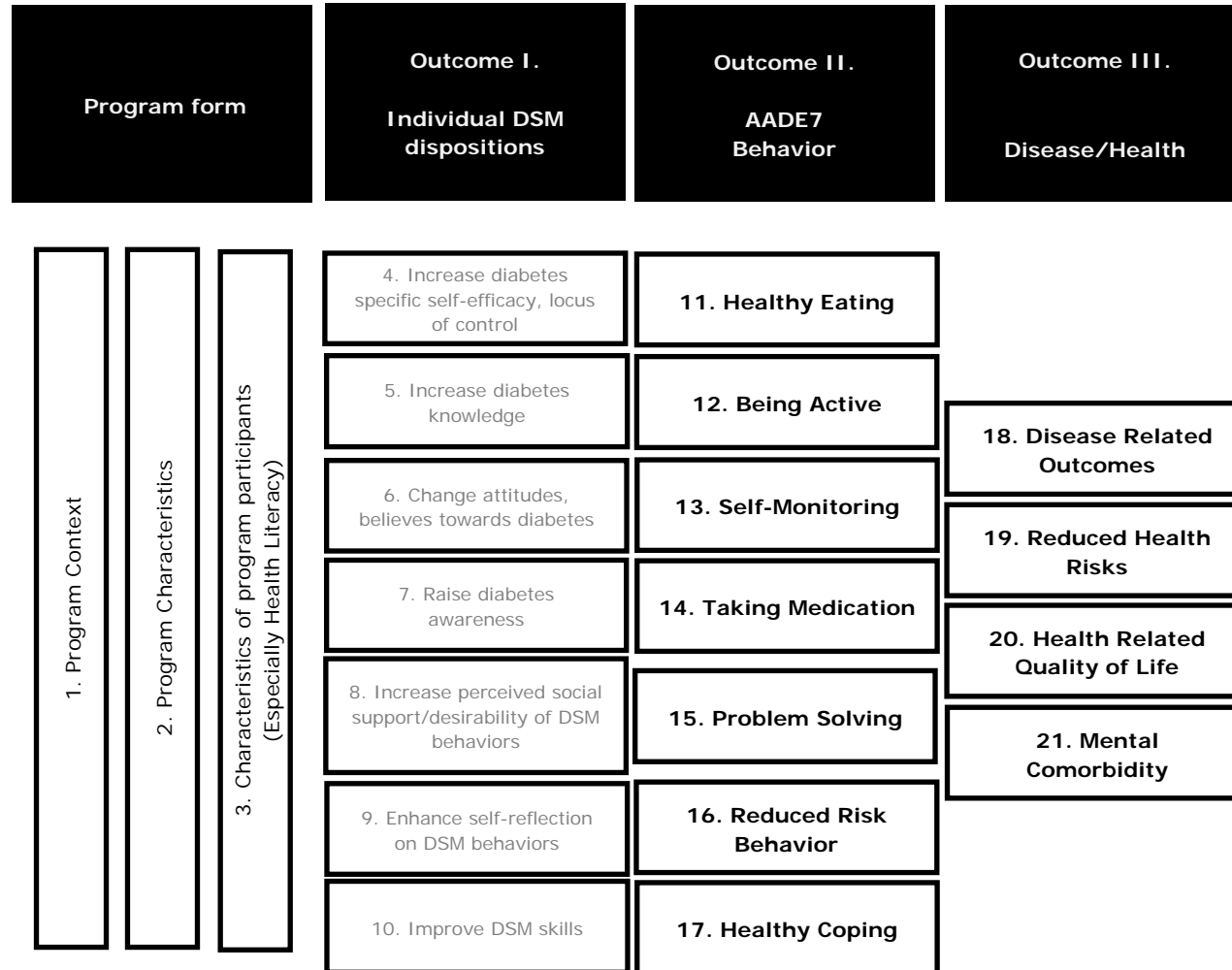
1. To assess the effectiveness of selected, existing diabetes self-management programs using different communication channels
2. To compare the relative effectiveness of these diabetes self-management programs
3. To investigate the role of health literacy in DSM and in program effectiveness
4. To investigate the role of other covariates
5. To investigate the impact of implementation fidelity on program effectiveness
6. To investigate organizational effectiveness of DSMPs



2. METHODS

Diabetes Self-Management Outcome Framework (DSMOF) - Outcome Elements and Sub-categories

(based on the AADE7 Framework) (AADE, 2008)



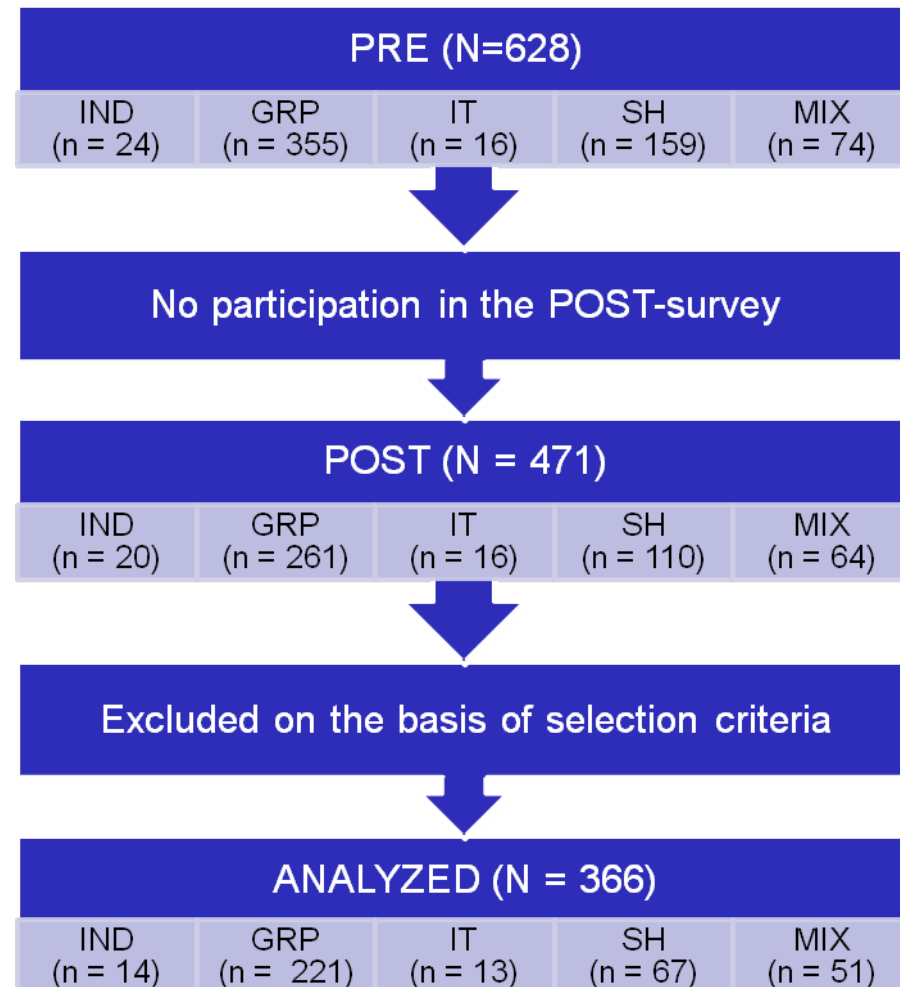
Roethlin, et al. 2013

Selected outcome indicators

DSMOF Outcome	DSMOF sub-category	Instruments
INDIVIDUAL DISPOSITIONS (DSMOF OUTCOME I)	Integrated measure of several individual DSM dispositions	Diabetes Specific Health Literacy Scale (DHL)
	Healthy Eating, Being Active, Self-Monitoring, Taking Medication, Reduced Risk Behavior	Summary of Diabetes Self-Care Activities Measure (SDSCA)
DIABETES BEHAVIOR (DSMOF OUTCOME II)	Problem solving	The Problem Areas in Diabetes Scale (PAID-5)
	Healthy Coping	Appraisal of Diabetes Scale (ADS)
HEALTH OUTCOMES (DSMOF OUTCOME III)	Reduced Health Risks	BMI
	Health Related Quality of Life	SF-36 Health Survey (Rand-Version)
	Well Being	WHO-5 Well-Being Index

Design and Recruitment of patient study

- Observational
- Multi-center, multi-national (B, D, DK, IRL, NL, A, UK) + Israel, USA and Taiwan
- Five armed
- Pre-post design
- Pooled analysis
- Imputation of missing data





3. RESULTS

Objective 1 - Absolute Effectiveness

Outcome	Mean (SD)	p	
General Healthy Eating	0.36 (1.91)	< .001	↑
Problem Solving	1.13 (4.30)	< .001	↑
Reduced Risk Behavior (Foot Care)	0.54 (1.53)	< .001	↑
Healthy Coping	1.06 (3.93)	< .001	↑
Reduced Health Risks	-0.31 (1.72)	< .001	↑
Health Related Quality of Life	4.17 (16.35)	< .001	↑
Well Being	2.54 (22.01)	.014	↑

Outcome	% PRE / POST	p	
Being Active	78% / 84%	< .001	↑
Taking Medication	88% / 92%	.021	↑

Objective 2 - Relative Effectiveness

IND vs. Other

Outcome	Difference ^a
Problem Solving	-5.478*
Reduced Risk Behavior (Foot Care)	-0.796*

Unstructured vs. Structured

Outcome	Difference ^a
Reduced Risk Behaviour (Foot Care)	2.018*

^a controlled for baseline measure and covariates

* $p < .05$; ** $p < .01$

GRP vs. IT and SH

Outcome	Difference ^a
Reduced Risk Behavior (Foot Care)	-2.38**

Outcome	Odds Ratio ^a
Self-monitoring	0.001*

MIX vs. Other

Outcome	Difference ^a
Reduced Risk Behaviour (Foot Care)	-0.331**

Objective 3 – Role of health literacy

1. There was a significant overall main effect of diabetes education on diabetes specific health literacy as an outcome
2. General health literacy had only a moderating effect on the absolute effectiveness of DSM programs regarding communicative diabetes health literacy.
3. Diabetes specific health literacy had no definite moderating effect on the relative effectiveness of programs.
4. Depending on different group comparisons positive as well as negative influences of diabetes specific health literacy on some indicators were found.

Objective 4 - Significant Influences of Covariates

Outcome	Covariate	Influence
General Healthy Eating	Diabetes Specific Health Literacy	↑
Diabetes Specific Healthy Eating	Age Diabetes Specific Health Literacy	↑↑
Self-Monitoring	Age	↑
Problem Solving	Social Status Migration General Health Literacy	↑↓
Reduced Risk Behavior (Foot Care)	Education Migration	↓↓
Healthy Coping	Migration General Health Literacy	↓↑
Well Being	General Health Literacy	↑
Diabetes Specific Health Literacy	Age	↓
Communicative Diabetes Specific Health Literacy	Social Status	↓

Objective 5 - implementation fidelity

Dependent variable	Adherence		Adaptation		F_{time}	$F_{adherence}$	$F_{interaction}$
	(Mean and SD)		(Mean and SD)				
	T ₁	T ₂	T ₁	T ₂			
DHL communicative	2.91 (.827)	2.83 (.738)	2.99 (.927)	2.75 (.879)	3.984*	.001	.883
DHL functional	3.18 (.684)	3.27 (.557)	2.78 (.828)	3.09 (.695)	6.475*	2.811	.842
DHL critical	3.09 (.755)	3.06 (.725)	2.59 (.962)	2.89 (.901)	9.570**	6.504*	10.765***
Diet	4.51 (1.592)	4.73 (1.306)	3.86 (1.679)	4.55 (1.35)	8.659**	3.687	1.898
Exercise	2.97 (2.494)	3.54 (2.369)	1.64 (1.963)	2.68 (2.331)	18. 634***	8.401**	1.564
Foot care	3.99 (1.647)	4.68 (1.285)	3.65 (1.848)	4.13 (1.653)	18.160***	3.412	.457
Problem	1.35 (1.092)	1.18 (1.068)	1.92 (1.231)	1.77 (1.311)	4.134*	9.082**	.019
Coping	3.64 (.624)	3.85 (.675)	3.29 (.698)	3.60 (.789)	22.331***	6.524*	.716
General health	3.24 (.709)	3.41 (.827)	2.79 (.826)	3.10 (.809)	18.366***	8.817**	2.288
Well-being	1.86 (1.141)	1.59 (1.071)	2.41 (1.368)	2.27 (1.204)	5.690*	10.336**	.137

Objective 6 - Results of the survey on organizational effectiveness of DSMPs

- Survey included DSMPs from inventory list generated from WP3 and some selected programmes (N=66, from 10 countries, 50% Dutch)
- 56% of programs were part of a larger host organizations:
 - 32% hospital,
 - 22% outpatient clinics
- Organizational effectiveness of DSM programs showed a mean score of 52 (47-56)% on a scale of 0-100%.
- Evaluation of services to strengthen competencies and excellence scored low.
- Participatory approach/Patient involvement scored especially low with 19%. In less than half of the organisations patients are involved in the organisation of DSMPs.



4. SUMMARY, LIMITATIONS AND CONCLUSIONS

Summary

1. DSM programs as a whole are absolute effective in changing behavior and improving psychological outcomes.
2. This study did not demonstrate systematic differences regarding the relative effectiveness of the different communication channels.
3. General health literacy has no moderating effect on the relative effectiveness of different channels, but has an moderating effect on the absolute effectiveness regarding communicative diabetes specific health literacy. Moderating effects of diabetes specific health literacy are inconsistent and need to be analyzed in more detail.
4. Covariates like age, migration status, social status, education, general health literacy and diabetes specific health literacy have an influence on some outcome indicators, but need further research.
5. Most of the intervention outcomes improved after the intervention, regardless of the provider's adherence to the program guidelines. For critical DHL as outcome, the provider's adaptations are associated with a greater improvement
6. There is quite some potential for improving organizational effectiveness, especially concerning use of evaluation of services for quality improvement and involvement of patients in organization of programs.

Limitations

- Observational study
 - Heterogeneity of existing DSM programs
 - Heterogeneity of countries / cultures
 - No information on program attrition
- Sample size
- Program fidelity only for a selection of programs
- Organizational effectiveness only for a small selection of programs

Proposed next steps for research

- ✓ Clinical trial including a control group
- ✓ Standardized DSM programs
- ✓ Consideration of cultural and individual context
- ✓ Inclusion of program fidelity & organizational effectiveness for all programs

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Contact:
Juergen.Pelikan@lbihpr.lbg.ac.at

LBIHPR: A-1020 Vienna, Untere Donaustraße 47, Austria | office@lbihpr.lbg.ac.at | www.lbihpr.lbg.ac.at | +43 1 2121493 -10 | FAX - 50

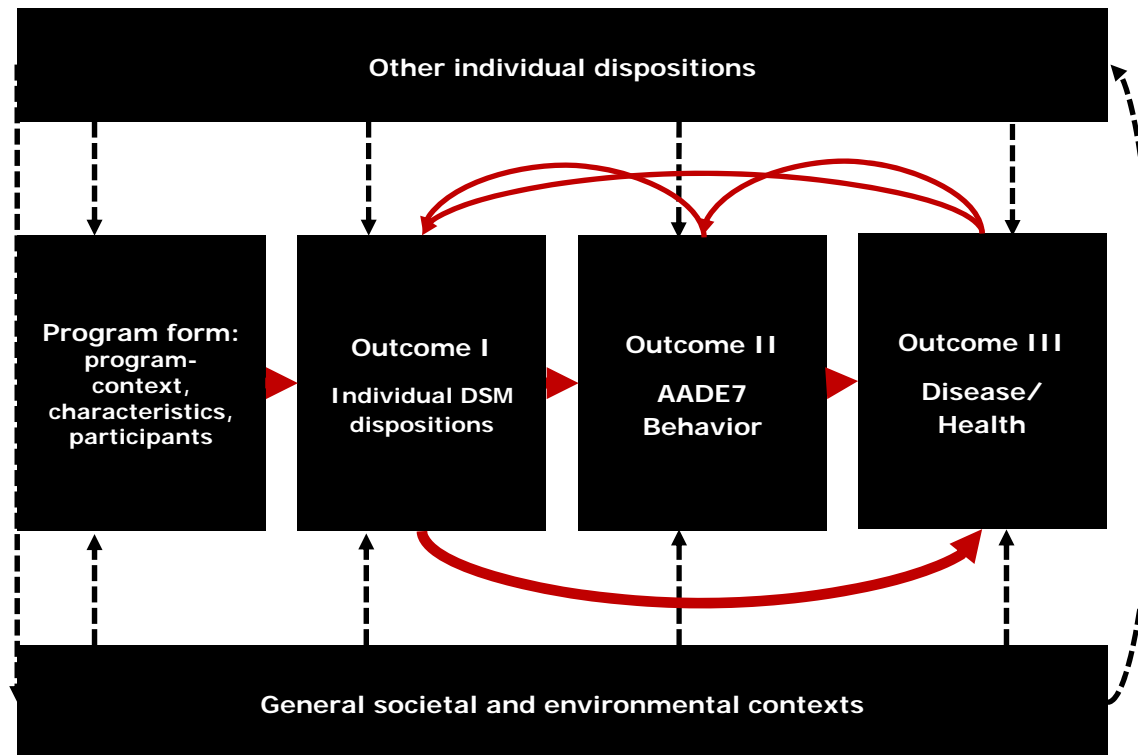
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Diabetes Self-Management Outcome Framework (DSMOF) Elements **(based on ...**





- ⑩ Implementation fidelity = the degree to which an intervention is delivered as intended
- ⑩ Diabetes education programs differ with regard to fidelity
 - ⌘ providers make adaptations of programs in terms of content, frequency, duration, intensity, or coverage
 - ⌘ can be considered as a mediator of program effectiveness
 - ⌘ > < need to adapt programs to the specific needs of patients and to the cultural and organisational context
- ⑩ Study of impact of IF on DSME effectiveness
 - ⌘ Questionnaire study on 33 providers from 16 different programs related to 166 diabetes patients involved in outcome study
 - ⌘ Distinction between an “total adherence” and “adaptation” group amongst the providers



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Conclusions on the role of implementation

- ⑩ Most of the intervention outcomes improved after the intervention, **regardless** of the provider's adherence to the program guidelines
- ⑩ For **critical DHL** as outcome, the provider's **adaptations** are associated with a **greater improvement**
 - Depends on type of adaptation: enhancement of critical DHL is seen when the provider changes the **coverage**, not when the provider changes the **content** of the program – here adherence enhances critical HL
- ⑩ Adherence also depends on the group's initial characteristics
 - participants in the “adherence” group had initially better critical DHL, were physically more active, reported better coping and a better general health, and perceived their diabetes as a less difficult problem than those in the adaptation group

WP6 Organisational effectiveness of DSMPs

- Survey among DSMPs from inventory list generated from WP3 and some selected programmes (N=66, 10 countries)
- Case study to gain in-depth insight from various practice examples of self/management (N=12 interviews, 9 countries)

B. Curriculum and guidelines	70 (63-76)%
(I) Easy access to care for people with diabetes	
C. Target groups	47 (40-55)%
D. Health literacy	56 (53-59)%
E. Personalized plans	66 (61-71)%
(II) Availability of healthcare professionals with multi-professional competences	
F. Implementation team and means	46 (40-52)%
G. Program management	61 (53-69)%
H. Workforce development	71 (60-82)%
I. Multi-professional competences	59 (51-67)%
(III) Availability of an efficient information system allowing for patient follow-up	
J. Patient progress monitoring	54 (43-64)%
(IV) Evaluation of services to strengthen competences and excellence	
K. Evaluation of services	35 (25-44) %
L. Quality assurance of organization	36 (27-45)%
M. Participatory approach/Patient involvement	19 (14-25)%
Overall Mean	52 (47-56)%

Case study results

Organisational characteristics

- Org. Structures and how the DSME is embedded varies between countries
- Curriculum and guidelines are widely implemented

Easy access to services

- DSME cover all profiles of diabetes. There is a need to sensitize to target groups with specific requirements
- Limited health literacy is rarely taken into account
- Personalised plans are often not considered in the design and implementation

Availability of cross-disciplinary teams

- Resources for implementation team and means are overall adequate
- Programme managers are characterized as qualified, passionate and enthusiastic
- Workforce development is important the engagement of patients in the DSME
- Multi-professional teams do exist, but may not be a critical factor for quality

Availability of information systems

- Patient progress monitoring is barely implemented

Evaluation of services

- Although there is an impression of success, systematic evaluation of services are not widely established
- The uptake of tools for quality assurance vary
- Although patient involvement is recognised, it is not implemented systematically

Policy recommendations

Room for improvement

- Integrate DSME in the standard chain of care
- Strengthen patient involvement
- Workforce development with a focus on co-production between patients and professionals

Winning strategies

- Evidence based DSME based on guidelines
- Diabetes champions
- Implementation team and means