EFFECT EVALUATION (WP8)

Erasmus MC
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CONFIDENTIAL! PRELIMINARY RESULTS

Co-funded by
the Health Programme
of the European Union

Goal WP8

The goal was to analyse the data and to evaluate the performance of the SEFAC program in the participating countries.

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Objectives

Main objective

- To appraise the SEFAC program in terms of benefits for the target population.

Research questions

- What are the effects of the SEFAC program on self-management, healthy lifestyle behavior, social support, stress, depression, sleep, fatigue, adherence to medication, and health-related quality of life (HR-QoL)?
- What are the societal cost savings of the SEFAC program in terms of reducing health care utilization and productivity losses among the target population?
- To what extent is the target population satisfied with the SEFAC program as a whole and with its three specific elements (mindfulness, social engagement, and ICT support)?

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Design, setting and procedures

- Pre-post design

- Target population: community-dwelling citizens of ≥50 years
  - with cardiovascular disease (CVD) and/or type 2 diabetes (T2DM)
  - or at increased risk of developing CVD and/or T2DM

- Data collection
  - Baseline (T0)
  - Follow-up at circa 6 months (T1)

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Data collection and measures

	Instrument	To	T1
Objective 1 (Health effects)			
Self-efficacy	6-item Self-Efficacy for Managing Chronic Disease scale (SEMCD) 10-item General Self-Efficacy Scale (GSES) 5-item Physical Exercise Self-Efficacy Scale (PESES) 5-item Nutrition Self-Efficacy Scale (NSES)	X	X
Lifestyle behaviours			
Physical exercise	6 items on physical exercise	X	X
Healthy eating	3 items on intake of fruits, vegetables, and breakfast	X	X
Sedentary behavior	1 item of the International Physical Activity Questionnaire (IPAQ)	X	X
Smoking	1 item (yes/no)	X	X
Alcohol use	1 item from the AUDIT-C	X	X
Social support	3-item Oslo Social Support Scale (OSSS-3)	X	X
Mental well-being			
Stress	10-item Perceived Stress Scale (PSS-10)	X	X
Depression	8-item Patient Health Questionnaire (PHQ-8)	X	X
Sleep problems	1 item (visual analogue scale)	X	X
Fatigue	1 item (visual analogue scale)	X	X

	Instrument	T0	T1
Objective 1 (Health effects)			
Medication adherence	6-item Short Medication Adherence Questionnaire (SMAQ)	X	X
Health-related quality of life	12-item Short-Form health survey EuroQol-5 Dimensions-5 level (EQ-5D-5L)	X	X
Objective 2 (Societal cost savings)			
Health care utilization	4 items from the Self-Management Resource Center (SMRC) Health Care Utilization questionnaire, regarding doctor appointments, emergency room visits, and hospitalized nights	X	X
Productivity losses	2 domains from the Productivity Costs Questionnaire (PCQ): lost productivity at paid work due to absenteeism (6 items) and lost productivity at unpaid work (3 items)	X	X
Objective 3 (Participant satisfaction)			
Evaluation	7 items on experiences with the SEFAC program	X	X
Satisfaction	1 item satisfaction with the SEFAC program	X	X

Data collection overview

Results from first 3 pilot sites (HR, IT and NL)

371

Engaged participants (engaged = attended at least 1 session)

343

Completed participants (=attended at least 4 of the 7 sessions)

352

Valid baseline questionnaire

325

Valid follow-up questionnaire

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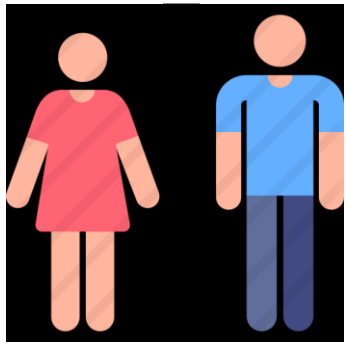
Participant characteristics

SEFAC participants



80% female
20% male

Mean: 67 y
SD: 7.9

Differences between pilot sites

Primary education level

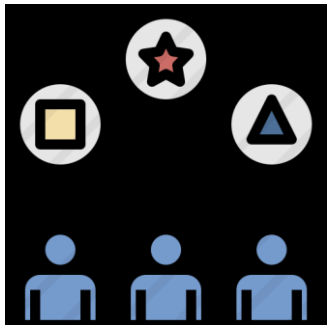
NL	1%
IT	29%
HR	18%

Paid job

NL	52%
IT	73%
HR	84%

Presence of T2DM / CVD

NL	57%
IT	27%
HR	25%



Migration back-ground

NL	15%
IT	5%
HR	19%

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Results – Objective 1 - Effects

What are the effects of the SEFAC program on self-management, healthy lifestyle behavior, social support, stress, depression, sleep, fatigue, adherence to medication, and health-related quality of life (HR-QoL)?

	n (paired)	Baseline	Follow-up	P-value
Self-efficacy				
SEMCD-6 (score range 1-10)	325	6.95 (1.59)	7.28 (1.70)	**<0.001**
GSES (score range 10-40)	324	30.45 (5.39)	31.85 (5.31)	**<0.001**
PESES (score range 5-20)	325	13.53 (3.91)	14.06 (4.13)	**0.021**
NSES (score range 5-20)	323	13.88 (3.68)	14.63 (3.68)	**<0.001**
Lifestyle behaviors				
Physical exercise				
Stretching/strengthening (min/wk)	319	48.90 (59.11)	46.13 (58.68)	0.415
Aerobic exercise (min/wk)	325	176.91 (112.39)	185.95 (120.98)	0.164
Walking (min/wk)	323	117.49 (65.84)	120.56 (64.97)	0.405
Swimming / aquatic (min/wk)	320	6.89 (27.16)	14.39 (42.13)	**<0.001**
Cycling (min/wk)	322	23.94 (47.56)	26.18 (50.03)	0.317
Other aerobic (min/wk)	321	12.90 (36.38)	10.05 (31.03)	0.140
Other exercise (min/wk)	307	17.69 (45.51)	16.66 (45.25)	0.735
Sedentary behaviour (week day) (h/wk)	323	5.63 (2.73)	5.33 (2.76)	**0.032**
Sedentary behaviour (weekend day) (h/wk)	323	6.24 (2.98)	5.63 (2.88)	**0.001**
Fruit, >1 portion/d	323	170 (52.6%)	186 (57.6%)	0.094
Vegetables, >1 portion/d	322	138 (42.9%)	151 (46.9%)	0.208
Having breakfast, >5 d/wk	325	277 (85.2%)	270 (83.1%)	0.281
Alcohol, 2 times/wk or more	325	83 (25.5%)	83 (25.5%)	1.000
Smoking, yes	325	33 (10.2%)	29 (8.9%)	0.219

	n (paired)	Baseline	Follow-up	P-value
Social support				
OSSS-3 (score range 3-14)	324	9.40 (2.22)	9.73 (2.26)	**0.002**
Mental well-being				
Stress (PSS-10; score range 0-40)	325	16.28 (5.94)	15.05 (5.66)	**<0.001**
Depressive symptoms (PHQ-8 ≥10)	324	57 (17.6%)	39 (12.0%)	**0.008**
Sleep problems (score range 0-10)	325	4.71 (2.61)	4.29 (2.60)	**0.004**
Fatigue (score range 0-10)	325	4.76 (2.28)	4.67 (2.38)	0.505
Medication adherence				
Medication adherence (SMAQ), no adherence	285	170 (59.6%)	156 (54.7%)	0.130
HR-QoL				
Health-related Quality of Life (HR-QoL)				
PCS Score (SF-12; score range 0-100)	323	44.80 (9.04)	45.97 (8.90)	**0.005**
MCS Score (SF-12; score range 0-100)	323	43.83 (8.88)	44.88 (8.01)	**0.021**
EQ-5D-5L utility values	324	0.80 (0.15)	0.82 (0.16)	**0.001**
EQ-5D-5L Overall health (score range 0-100)	325	70.85 (16.61)	73.87 (17.46)	**0.001**

Results – Objective 2 – Cost-effectiveness

What are the societal cost savings of the SEFAC program in terms of reducing health care utilization and productivity losses among the target population?

Cost-effectiveness analysis with a time horizon of 6 months

1. Healthcare perspective
2. Societal perspective

Results – Objective 2 – Healthcare perspective

This perspective takes healthcare costs into consideration

Table on the resource use of participants of the SEFAC project at T0 and T1

	n (paired)	Baseline	Follow-up	P-value
Doctor appointments	325	3.57 (4.87)	2.64 (3.69)	**<0.001**
Hospital emergency room visits	325	0.21 (0.57)	0.16 (0.79)	0.345
Hospitalized nights	313	0.20 (1.18)	0.34 (2.43)	0.383

Calculations using unit prices of the three resources →

Estimated saving of healthcare costs →

Average saving for the 3 pilot sites was **55 euro** per participant

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Results – Objective 2 – Societal perspective

This perspective takes productivity losses into account

- Lost productivity at paid work due to absenteeism
- Lost productivity at unpaid work

Paid work

Calculations using number of hours absent from work due to illness & hourly cost prices → Estimated saving of productivity costs →

Average saving for the 3 pilot sites was **153** euro per participant

Unpaid work

Calculations using number of hours required to take over the unpaid work unable to do & hourly cost prices → Estimated saving of productivity costs →

Average saving for the 3 pilot sites was **636** euro per participant

Combined:
Average saving for the first 3 pilot sites was **789 euro** per participant

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Results – Objective 2 – Both perspectives

Healthcare perspective

The weighted average is a saving of **55 euro** per participant.

Societal perspective

The weighted average is a saving of **789 euro** per participant.

Combined

The weighted average is a saving of **844 euro** per participant.

Results – Objective 3 - Satisfaction

To what extent is the target population satisfied with the SEFAC program as a whole and with its three specific elements (mindfulness, social engagement, and ICT support)?

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Satisfaction with the SEFAC program at follow-up

- The majority of participants considered the SEFAC program beneficial and worthwhile (>81%).
- 75% or more of the participants reported that the three components of the program stimulated them to work on a healthy lifestyle.
- More than 75% of the participants reported an improvement in self-awareness.
- The average satisfaction score was 8.2 (SD 1.56) on a scale from 1 to 10; all countries rated the SEFAC program above 7.5.
- Participant satisfaction with the program was lower in the Netherlands as compared to Croatia and Italy.

Discussion

Strengths	Limitations
Adapted mindfulness-based program in the field of lifestyle medicine	Absence of a control group
Good acceptability and feasibility with low participant drop out (12%)	Number of topics included in the questionnaire was limited
Four distinct countries across Europe	All outcomes were self-reported
Diverse study sample in both socioeconomic background and educational level	Limited follow-up period
	Cost-effectiveness analyses need to be interpreted with caution
	Influence of the COVID-19 pandemic

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Conclusion

- The SEFAC program can support self-management skills of persons ≥50 years with or at risk of CVD and/or T2DM.
- The SEFAC program showed significant improvements on self-efficacy, social support, and HR-QoL, and statistically significant reductions in stress, depression, sleep problems, and sedentary behavior.
- Results on cost-effectiveness should be interpreted with caution.
- The overall satisfaction score of the SEFAC program was high.
- Additional strategies or a longer application of the SEFAC program may be required for improvements of relevant health behaviors.
- It is recommended to evaluate an extended SEFAC program, with a focus on mindfulness as well as lifestyle behaviors, by means of a randomized controlled trial in a varied population with a longer follow-up period and including objective physical health outcomes in addition to self-reported questionnaires.

Thank you!

SEFAC

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Co-funded by
the Health Programme
of the European Union