Original Communication

Weight Control With Orlistat in a Telephone-Counseling Program

Simone Munsch, Andrea H. Meyer, and Jürgen Margraf

University of Basel, Switzerland

In this study, we aimed to describe the effectiveness of a short-term telephone-counseling program in combination with orlistat in overweight and obese outpatients and to test the influence of pre-treatment characteristics on weight-loss goals and achieved weight change. A total of 655 patients were contacted every 6 weeks, receiving an average of 5.2 telephone calls. Patients lost on average 7.7% of their initial weight during treatment. Reported weight-loss goals amounted to 17.8% of initial weight. Desired weight loss was positively related to weight at program start and age. Achieved weight loss was positively related to weight at program start, but not to sex and age. Low-intensity telephone treatment in combination with orlistat induced weight loss in an outpatient sample. At the end of treatment, patients judged lower-than-desired weight loss as satisfactory. Setting high weight-loss goals was a positive predictor of weight loss. However, long-term maintenance remains unclear.

Keywords: obesity, orlistat, telephone counseling, weight loss, path analysis

Obesity (body mass index, BMI > 30 kg/m^2) is a chronic disorder, which is associated with the risk of subsequent diseases and distinctly elevated mortality. Apart from a wide number of medical complications (Manson et al., 1995; Stevens et al., 1998), obesity is frequently associated with labeling and negative consequences in psychosocial areas (Latner & Stunkard, 2003). Additionally, obesity is characterized by an elevated risk for developing eating disorders, especially binge eating disorder (Wilfley, Wilson, & Agras, 2003) and anxiety and mood disorders (Becker, Margraf, Turke, Soeder, & Neumer, 2001). Roughly 20 to 30% of the US population and about 10 to 20% of the European population are affected by obesity (Flegal, Carroll, Ogden, & Johnson, 2002; Munsch, 2002; Visscher & Seidell, 2001).

Current approaches emphasize an individualized and multimodal approach based on diet, exercise, and behavior change (Perri & Corsica, 2002). Weight loss can be induced and supported by additional pharmacotherapy. Orlistat, a minimally absorbable (< 1%) agent that inhibits activity of pancreatic and gastric lipases, blocks gastrointestinal uptake of approximately 30% of ingested fat (Davidson et al., 1999). Orlistat has been shown to promote short-term weight loss and to be effective in lessening weight regain when combined with dietary interventions (Bray, 2002; Davidson et al., 1999; Hauptman, Lucas, Boldrin, Collins, & Segal, 2000; Sjostrom et al., 1998).

Several studies have investigated pre-treatment determinants of weight loss and maintenance. Pre-treatment BMI has been found to be a stable predictor of short- and long-term weight-loss success (Bild et al., 1996; Hoie & Bruusgaard, 1999), also in pharmacological and surgery trials (Dixon, Dixon, & O'Brien, 2001; Hansen et al., 2001; Womble, Williamson, Greenway, & Redmann, 2001). Higher initial BMI, due to higher energy expenditure, is associated with higher weight loss during treatment trials (Hansen et al., 2001; Womble et al., 2001). With respect to age and sex, the study results are contradictory as some found predictive values (Hjartaker, Laake, & Lund, 2001; Honas, Early, Frederickson, & O'Brien, 2003) and some did not (Dixon, et al., 2001; Hansen et al., 2001).

Another major factor influencing weight loss and weight-loss maintenance is the setting of weight-loss goals. Whereas there is considerable professional consensus that weight losses of 5% to 10% are realistic (Foster, Wadden, Phelan, Sarwer, & Sanderson, 2001), desired weight losses of obese patients are 3 to 4 times higher (a 22–34% reduction in body weight) than those recommended by professionals (Wadden et al., 2000). It is further known that patients with the highest pre-treatment weights are likely to have the most unrealistic expectations for success (Foster et al., 2001). Several studies have suggested that patients who achieve their target weight may be more successful at long-term weight maintenance (Byrne, 2002; Byrne, Cooper, & Fairburn, 2003), but other studies did not support these findings (Jeffery et al., 1998).

Because of the chronic nature of obesity, most treatment

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programs involve a substantial individual face-to-face treatment. Such interventions are cost intensive, and it may be impractical to treat the large number of patients and at-risk individuals (Wadden & Sarwer, 1999). New methods for providing and delivering treatment are needed to ensure that patients with obesity have access to long-term care (Wadden et al., 1997). For example, a one-year pilot study (Wadden et al., 1997) found that a short-term structured Cognitive Behavioral Treatment (CBT) program delivered by physicians with adjunctive pharmacological therapy was as effective as a standard long-term CBT program with adjunctive pharmacological therapy. Furthermore, home-based weight-regulation programs show better adherence, particularly when combined with brief instructions, internet, and regular telephone or e-mail contact (Jeffery et al., 2003; Tate, Jackvony, & Wing, 2003). However, a recent review of obesity treatment options in medical care settings concluded that, at present, the effectiveness of such low-intensity treatment remains uncertain and emphasized the need for further research targeting this question (Harvey, Glenny, Kirk, & Summerbell, 2003).

In the following, we will present the results of a telephone-guided self-help treatment program for a sample in Switzerland of physician-referred overweight and obese outpatients medicated with orlistat. We investigated the effectiveness of this treatment, which can be viewed as an alternative to face-to-face treatment. Using a path analytic model, with which more complex relationships among the patient characteristics measured could be tested, we tested the influence of pre-treatment determinants, such as weight and height at program start, age, and sex, on desired weight loss and achieved weight change.

Method

Telephone Treatment and Medication

Patients from all over Switzerland who had been enrolled by their physicians in a treatment program called XLine (sponsored by F. Hoffmann-La Roche Ltd., Switzerland) by XLine telephone counselors were contacted within a few days. Those contacted were at least 18 years of age. Patients with chronic malabsorption or cholestasis as well as pregnant or nursing women were excluded from treatment. During the first phone call, data were collected on weight, height, and somatic risk factors as well as nutrition, eating habits, and physical activity patterns. In addition, the dose, duration, and possible side effects of orlistat were discussed. The counselor informed the patient about feasible weight-loss goals, and then they explicitly agreed on a personal weight-loss goal for the patient and the time required to achieve it. After this initial phone call, patients were sent treatment materials concerning nutrition and physical activity by mail (fat table, booklet on low-fat cooking, physical activity table). At the end of the initial telephone call, an one-month follow-up appointment was arranged. Patients were contacted every 6 weeks, receiving an average of 5.2 phone calls by the end of treatment. Telephone counselors (nurses, dieticians) were trained in communication skills and supervised by PhD clinical psychologists on a regular basis. Physicians prescribed the recommended therapeutic dose of orlistat (120 mg 3 times a day).

Participants

The sample consisted of 842 patients, of whom 108 did not fulfill inclusion criteria (e.g., BMI < 28), 26 dropped out due to gastrointestinal disorders, and 53 dropped out due to reasons unrelated to orlistat or the XLine program. Of the remaining 655 patients beginning the telephone treatment, 23.4% (n = 153) were male and 76.6 % (n = 502) female. The average BMI at program start was 36.6 (N = 655; SD = 5.0). Table 1 shows the sample characteristics.

Statistical Analysis

Data collection and telephone treatment were carried out by Outcomes International, Basel, Switzerland. Patients reported their weight to the telephone counselors. To check the precision of patients' self-reported weight, data collected in a pilot project on patients' self-reported and physician-measured weight at similar time points were compared; a very high correlation between the two was found (linear regression between self-reported and physician-measured weight with intercept and slope not significantly different from 0 and 1, respectively, r = 0.98, N = 198).

Using the computer program AMOS (Arbuckle, 1997), we developed a path model containing the following variables: patient's sex, height, age, and weight at program start, duration of orlistat treatment before program start, desired weight loss (difference between weight at program start and desired weight at program end), and achieved weight change (actual weight change between program start and program end). Path models can be seen as an extension of multiple regression models (e.g., see Kline, 1998). They assume causal relationships among different observed variables and are usually presented in diagrammatic form. Fig-

Table 1
Baseline Characteristics of All Variables Used in the Path Model

Sample characteristics	*Mean*	*SD*	*N*
Age at program start (years)	49.0	12.60	654
Height (cm)	166.0	8.61	655
Weight at program start (kg)	100.9	16.24	655
Duration of orlistat treatment (weeks; log-scale)	3.66	0.55	655
Desired weight loss (kg)	18.1	9.45	646
Achieved weight change (kg)	7.89	5.92	654

Note. SD = standard deviation.

ure 1 shows the path diagram that was used to analyze the data. Path models allow one to estimate regression coefficients (the *path coefficients*) and test the overall fit of a model. They distinguish between direct effects (e.g., in Figure 1, the single path between weight at program start and achieved weight change) and indirect effects (e.g., in Figure 1, the path from weight at program start to achieved weight change via desired weight loss). Of particular interest in this study are the paths leading to the achieved weight change and the desired weight loss. The model basically assumes that the patient's achieved weight change between program start and program end is directly affected by patient's sex, height, age and weight at program start and is indirectly affected by the same variables via the desired weight loss. The variable denoting the duration of treatment before program start may be thought of as a control variable that is important in order to make the other exogenous variables comparable with respect to it. This variable was log-transformed to reduce skewness and normalize the data.

Missing values were estimated using a full information maximum likelihood (FIML) approach, which is the default option in AMOS (Wothke, 2000). In the following, we report the results of the unstandardized coefficients.

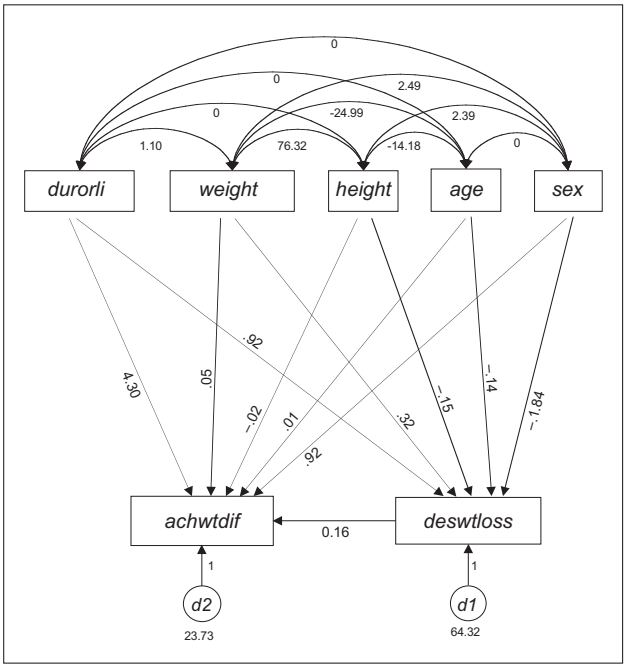

Figure 1. Path diagram of the model used to describe the data from the Xline program. Numbers next to single arrows denote path coefficients. Numbers next to double arrows denote covariances among endogenous variables. Numbers below the terms *d1* and *d2* denote variances of the disturbance terms. *sex* = patient's sex, *age* = age at program start (years), *height* = patient's height (cm), *weight* = weight at program start (kg), *durorli* = duration of orlistat treatment (weeks; log-scale), *deswtloss* = desired weight loss (kg) between program start and program end, *achwtdif* = achieved weight change (kg) between program start and program end.

Results

Patients spent on average 33.6 weeks in the counseling program (± 0.62 weeks[1]; $N = 655$). Their average weight was 100.9 kg (± 0.63 kg; $N = 655$) at the start and 93.0 kg (± 0.60 kg; $N = 654$) at the end of program, which corresponds to an absolute weight loss of 7.9 kg (± 0.23 kg; $N = 654$), a relative weight loss of 7.7% (± 0.22%; $N = 654$), and an estimated effect size (Cohen's *d*) of 1.33. The average desired weight loss was 18.1 kg (± 0.37 kg; $N = 646$), which corresponds to a relative desired weight loss of 17.8% (± 0.31%; $N = 646$). Thus, patients intended to lose approximately 2.3 times more weight than they actually did. Almost two thirds of the patients (65.9%) lost at least 5% of their body weight, over a quarter (28.9%) at least 10%, and a few (2.9%) at least 20% during the program. Most patients (97.2%) intended to lose at least 5% of their body weight, a vast majority (83.0%) at least 10%, and over a third (34.5%) at least 20% by the end of treatment. The frequency distributions of achieved and desired weight loss (relative and absolute) and absolute loss in BMI are shown in Figure 2 and Table 2. Achieved relative weight change ranges from –13.6% (weight gain) to 27.2% (weight loss), whereas desired relative weight loss exhibits a wider range, namely from 0 (no intended weight loss) to over 47.8% (Figure 2). Frequencies for achieved absolute weight change and for change in BMI follow patterns similar to that of relative weight loss (Table 2). Of the 43 patients who did not lose weight, 22 (51%) did not gain weight either. The weight of the 21 weight gainers (3.2% of the total sample) increased on average by 2.6 kg ($SD = 3.0$). The proportion of females among the weight gainers (76.2%) was nearly identical to that among the weight losers (76.1%). The maximum weight gain observed was 11 kg (13.6%). Of the 655 patients investigated, 350 (53.4%) considered the Xline program successful; the remaining 305 (46.6%) considered it not successful. The average achieved relative weight change was 9.8% (± 0.30 %) for "successful" patients and 5.3% (± 0.26 %) for "not successful" patients.

Path Model

The path model was recursive and overidentified, so model parameters could be estimated (Kline, 1998). The overall fit of the model (see Figure 1) was good, $\chi^2(4) = 2.8$, $p = .60$, RMSEA < .0001, and accounted for 32% of the variance in achieved weight change and 28% of the variance in desired weight loss, which were the two endogenous variables.

Patient's desired weight loss was significantly influenced by age but only marginally by sex. Direct and total effects were identical for both age and sex as no indirect effects

1 Numbers following the ± characters denote plus/minus one Standard Error.

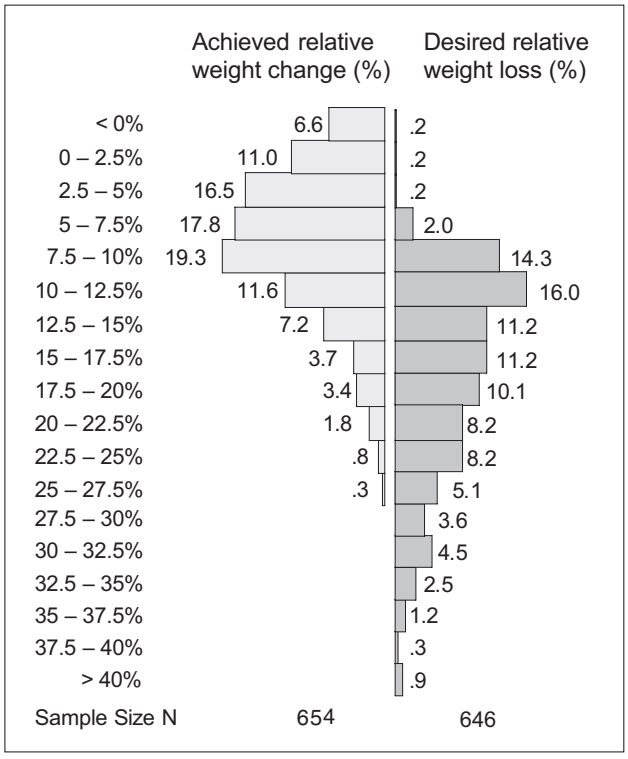

Figure 2. Frequency distributions for achieved relative weight change and desired relative weight loss. Numbers next to the horizontal bars denote the proportion of patients in each relative weight class to the total number of patients (= sample size).

Table 2
Frequency distributions for (a) achieved absolute weight change and (b) achieved absolute change in BMI
(a) Achieved absolute weight change (kg)

	Frequency	Percent
Total	654	
< 0 kg	43	6.6
0–2.5 kg	83	12.7
2.5–5 kg	113	17.3
5–7.5 kg	101	15.5
7.5–10 kg	121	18.5
10–12.5 kg	74	11.3
12.5–15 kg	50	7.7
15–17.5 kg	26	4.0
17.5–20 kg	15	2.3
20–22.5 kg	11	1.7
22.5–25 kg	9	1.4
25–27.5 kg	6	.9
30–32.5 kg	1	.2

(b) Achieved absolute change in BMI

	Frequency	Percent
Total	654	
< 0	43	6.6
0–1	88	13.5
1–2	119	18.2
2–3	121	18.5
3–4	119	18.2
4–5	71	10.9
5–6	35	5.4
6–7	27	4.1
7–8	17	2.6
8–9	8	1.2
9–10	3	.5
> 10	3	.5

were initially set up in the model for desired weight loss. The path coefficients for patient's age and sex were $b = -0.138$ ($\pm$ 0.025; $p < .001$) and $b = -1.84$ ($\pm$ 0.1.00; $p = .064$), respectively. Thus, after controlling for all other variables in the model, we found that, with each additional year of age, patients intended to lose approximately 0.14 kg less weight by the end of program. Also, the higher the patient's weight at program start, the higher his desired weight loss ($b = 0.316 \pm 0.023$; $p < .001$). So, in absolute terms, heavier patients wanted to lose more weight than lighter patients did. Interestingly, the path coefficient between desired weight loss and achieved weight change was strongly and significantly positive (0.157 ± 0.024; $p < .001$). Remember that this coefficient was obtained by correcting for all variables shown in Figure 1. Thus, patients who wanted to lose more weight actually lost more weight.

Heavier patients lost significantly more weight than lighter patients: The direct effect of weight at program start on achieved weight change was 0.053 ($\pm$ 0.016; $p < .001$) and its total effect (direct plus indirect effect) 0.103 ($\pm$ 0.015; $p < .001$). The latter result means that, for each additional kilogram of weight at program start, patients actually lost on average 0.103 kg more by the end of program. Half of this additional loss (i.e., 0.053 kg) is directly related to the patient's higher weight; the other half (0.050 kg, the difference between 0.103 and 0.053) is an indirect effect resulting from the above-mentioned findings that (a) patient's weight at program start positively affected desired weight loss and (b) desired weight loss positively affected achieved weight change.

Neither patients' sex nor age had a significant direct effect ($b = 0.920 \pm 0.603$ for sex and $b = 0.006 \pm 0.015$ for age) or a significant total effect ($b = 0.622 \pm 0.621$ for sex and $b = -0.016 \pm 0.016$ for age) on achieved weight change ($p > .1$ for all four tests). Thus, after all other variables in the model had been controlled for, there was no indication that patient's sex or age was an important determinant of achieved weight change by the end of program.

Discussion

Our main findings indicate that a telephone-counseling program in combination with orlistat treatment resulted in self-reported weight loss in obese outpatients. In our study, pa-

tients lost on average 7.7% of their initial weight during the 33.6 weeks of treatment. 65.9% of the patients reached 5%, and 28.9% reached 10% weight loss during the program. The weight losses obtained in our patient sample are in line with the results of more intensive face-to-face treatment programs (Hauptman et al., 2000; Krempf et al., 2003) in which the effectiveness of orlistat in promoting weight loss was underscored. Recent long-term studies have reported a relative weight loss of at least 5% in over 50% of the patients medicated with 120 mg orlistat 3 times a day (Hauptman et al., 2000; Krempf et al., 2003). An additional 28.6% (Hauptman et al., 2000) and 32.9% (Krempf et al., 2003), respectively, of these patients lost over 10% of their initial body weight in one year. Thus, this low-intensity intervention delivered by telephone in combination with orlistat treatment can be said to be effective in the short term. This is underscored by the high effect size found in this study (Cohen's $d = 1.33$). Future studies should account for cost effectiveness and compare the Xline treatment cost of 179.51 Swiss francs (CHF) per kilogram weight loss during the 33.6 weeks of treatment with face-to-face treatment trials. The value of 179.51 CHF was obtained as follows: [33.6 (weeks) * 7 (days) * 3 (doses) * 1.558 CHF (price per capsule) / 7.9 kg (average weight loss)] + 40.35 (approx. cost of the telephone-counseling program, including cost of apparatus, materials, and counselors' salaries during treatment, per kg weight loss).

Furthermore, we found specific pre-treatment patient characteristics that influence the outcome. Heavier patients lost more weight in absolute terms than lighter patients, which is in agreement with previous studies (Dixon, et al., 2001; Hansen et al., 2001; Womble et al., 2001). On the one hand, this might be due to higher initial weight and the associated higher energy expenditure (Hansen et al., 2001; Womble et al., 2001) (direct effect in our path model). On the other hand, we were able to show that heavier patients wanted to lose more weight and that, on average, these patients actually lost more weight (indirect effect in our path model). Contrary to others (Hjartaker et al., 2001; Honas et al., 2003), we found that, after we controlled for variables such as weight and height, achieved weight change by the end of program was independent of patient's sex or age.

Our patients' goal was to lose on average 17.8% of their initial weight. This value is close to that judged to be a disappointing amount of weight loss (15.6%) in a study in which patients also judged 24.9% to be an acceptable, 30.9% a happy, and 38.4% a dream amount of weight loss (Foster, Wadden, Vogt, & Brewer, 1997). Therefore, the initial counseling in our study, which was intended to help patients set feasible weight-loss goals, seems to have been effective in diminishing unrealistic outcome expectations. Admittedly, weight-loss goals are expected to be lower in low-intensity treatment programs like this than in programs with surgical treatment (Kral, 1998).

In our study, when asked at the end of treatment, the majority of patients (53.4%) judged their achieved weight change to be successful even though their average weight change amounted to "only" 9.8%. The relationship between satisfaction with weight loss and maintenance of weight loss has not yet been directly tested (Jeffery et al., 1998). Our findings demonstrate that patients can lessen their outcome expectations at treatment start and in the end judge lower-than-desired weight losses as satisfactory. These results question the assumption that satisfaction (defined as the discrepancy between expected and actual outcomes) generally affects subsequent success (Carver & Scheier, 1982; Cervone, Jiwani, & Wood, 1991). Future studies should investigate whether the discrepancy between expected and actual outcomes affects long-term maintenance of weight loss.

In view of the contradictory results regarding the influence of weight-loss goals on weight loss (Byrne et al., 2003; Foster et al., 1997; Jeffery et al., 1998), we were particularly interested in how goal setting influences treatment success. Unlike others (Jeffery et al., 1998), we found that the intention to lose more weight was not a negative predictor of weight loss. On the contrary, patients who wanted to lose more weight in the XLine program did indeed lose more weight. Whether patients with higher weight-loss goals maintain this weight loss in the long term is not clear although there are results in the literature indicating that they do (Jeffery et al., 1998). One should keep in mind that there may be an expectancy effect intervening with the results: Patients participating in the XLine program might expect to lose weight and thus be inclined to report unrealistic weight losses to their counselors.

There are several limitations to our study warranting consideration. First, neither for the effect of the medication with orlistat nor for the effect of telephone counseling was there a random assignment of participants to either a treatment or a control (waiting list or placebo) group. Therefore, the effects of pharmacotherapy and self-help treatment cannot be disentangled. Furthermore, we do not have any information about the recruitment procedure or additional interventions during Xline treatment (e.g., physician visits). In addition, we cannot rule out that patients' participation in the Xline program resulted in increased motivation (Hawthorne effect) and consequently higher-than-expected weight losses. Furthermore, we were not able to control for the attrition rate. As mentioned by Tsai, Wadden, Womble, and Byrne (2005), the results reported here are probably just the best-case scenario.

As did Ávila-Funes, Gutiérrez-Robledo, and Ponce de León Rosales (2004) in their national survey in Mexico, we found a very high correlation between self-reported and physician-measured weight in our pilot study. In contrast, other large national surveys conducted in the US (Flegal et al., 2002; Mokdad et al., 2003) showed a disparity between self-reported and other-recorded weight. Our treatment-seeking patients may therefore represent a special group that has a trusting relationship with the telephone counselors, resulting in their weight reports being more precise than those of the general population. However, one has to keep in mind that only using physician-measured weight for the whole study sample would strengthen the validity

of self-reported BMI considerably. It could be argued that the weight loss reported in this study might only reflect the "regression towards the mean" described, for example, by Kirkwood and Sterne (2003). However, there is evidence for spontaneous weight gain rather than weight loss in non-treatment-seeking obese populations (Jeffery et al., 2000). Furthermore, we do not know if and how patients in the telephone treatment program maintain their weight loss. In the literature, it is a generally accepted fact that, in time, weight regain will occur after treatment ends (Jeffery et al., 2000). Clearly, there is a great need for future research to develop ways to keep patients participating actively in weight control activities over a long period. Apart from these limitations, the data of the present investigation demonstrate for the first time that a low-intensity self-help treatment in combination with orlistat can induce weight loss in a sample of overweight and obese outpatients treated by physicians.

Author Note

Simone Munsch, Department of Psychology, University of Basel, Switzerland; Andrea H. Meyer, Department of Psychology, University of Basel, Switzerland; Jürgen Margraf, Department of Psychology, University of Basel, Switzerland.

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Simone Munsch

Fakultät für Psychologie
Abteilung Klinische Psychologie und Psychotherapie
Missionsstraße 60/62
CH-4055 Basel
simone.munsch@unibas.ch