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Original Article

# Men’s Access to Outpatient Psychosocial Cancer Counseling

## A Cluster-Randomized Trial

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### Summary

**Background:** Men make use of outpatient cancer counseling less commonly than women, even when they stand to benefit from it.

**Method:** In a cluster-randomized trial (registered under DRKS00032181), we studied whether measures on multiple levels (information for referring physicians, public information, structural changes, offerings specifically for male patients) over a period of 12 months would be able to increase the percentage of men among patients seeking outpatient cancer counseling (primary endpoint, initial contact; secondary endpoint, all contacts). The intervention effect was quantified by the fitting of generalized linear mixed models to obtain an odds ratio, which was adjusted for cluster structure and for the percentages of first contacts and of all contacts during the 12 months before the start of the intervention.

**Results:** In 12 regions of Germany (6 each in the intervention arm and the control arm), 11 986 people had first contacts with outpatient cancer counseling, 6004 of them during the intervention phase. The percentage accounted for by men was 30.7% in the intervention arm and 25.7% in the control arm, corresponding to a statistically insignificant model-based adjusted odds ratio (OR) of

1.2 (95% confidence interval [1.0; 1.4],  $p = 0.08$ ) for the primary endpoint. There were a total of 51 842 counseling sessions (both initial contacts and subsequent contacts), 26 651 of them in the intervention phase. The percentage of these that was accounted for by men was 27.6% in the intervention arm and 22.2% in the control arm; the adjusted OR for this secondary endpoint was 1.3 [1.1; 1.6],  $p = 0.01$ .

**Conclusion:** The targeted implementation of male-specific measures on multiple levels can increase, by a small amount, the percentage of men among persons seeking outpatient cancer counseling.

**Cite this as:**

Singer S, Wunsch A, Ihrig A, Bruns G, Holz F, Jakob J, Bessler M, Engesser D, Blettner M, König J, Bayer O: Men’s access to outpatient psychosocial cancer counseling—a cluster-randomized trial. *Dtsch Arztebl Int* 2024; 121: 121–7. DOI: 10.3238/arztebl.m2024.0005

Health services must be utilised in order to be effective. However, fewer men than women take advantage of the services on offer. This is true for preventive measures (1), for psychotherapy (2–5), and for cancer counseling (6–9). Psychotherapy, in particular, is tried only when all other measures have failed and the symptoms have reached crisis level (10). Men are also less likely to raise mental problems with primary-care physicians, and when they do, the consultations are shorter (11).

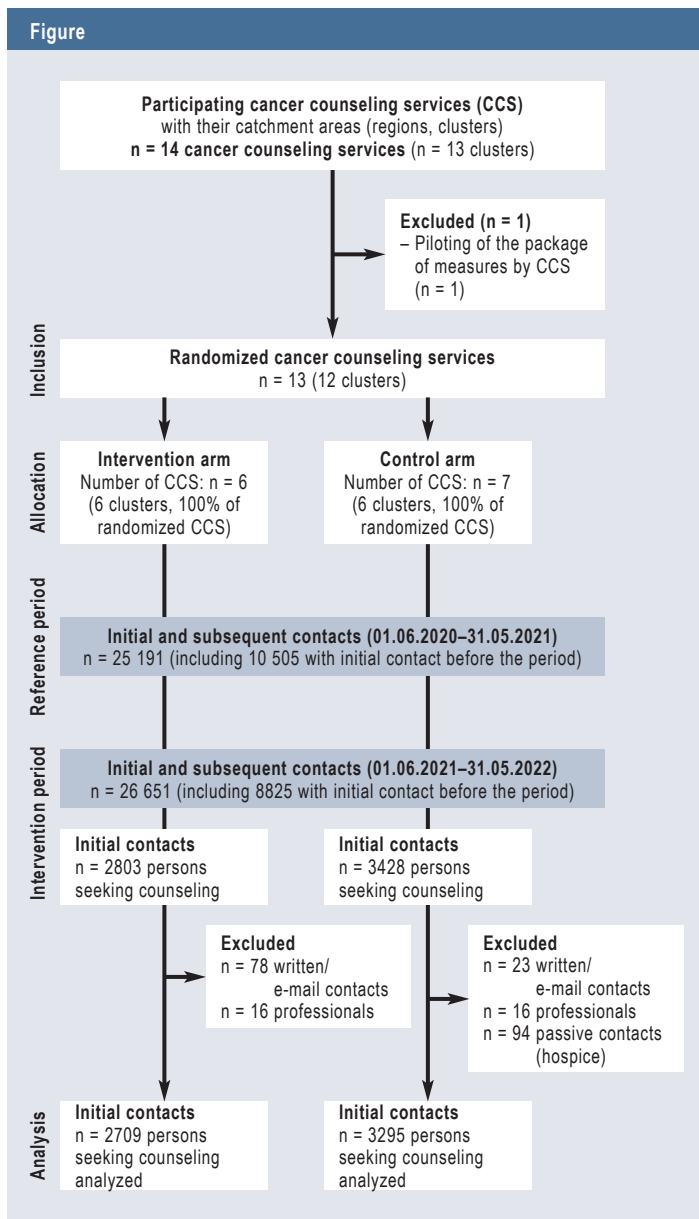
This can be explained by sociocultural norms, sex-specific experience of healthcare, and structural conditions (12–16). These three areas are mutually determinative and reinforcing, so it is not easy to alter this healthcare reality. However, some successful examples show that change can be achieved. The program “1000 Mutige Männer für Mönchengladbach” (1000 Brave Men for Mönchengladbach), for instance, increased men’s participation in cancer screening by 7% (17). In Edmonton, Canada, weekly floor hockey games organized by hospital staff established new perceptions of masculinity and self-care in the target

group—low-income, homeless, indigenous men (18). In Australia, men’s health-related self-efficacy and physical activity was improved by participation in the health promotion program “Sons of the West”, offered in cooperation with the Western Bulldogs Football Club (19).

Common to all of these measures is that:

- They were carefully planned and therefore “adjusted the right screws.”
- They were properly financed.
- They continued long enough.

In Mönchengladbach, for example, work with focus groups revealed that if men are to be motivated to take part, they have to be addressed personally by their family doctors and their partners. The physicians also received specific training for these conversations. The Canadian initiative was accompanied by years of ethnographic field research



Flow chart of the study design

(18). Another important point was that the floor hockey games were supervised by the same social worker (who was paid for this activity) over a period of more than 20 years.

Similarly, we conducted a pre-study in which qualitative interviews were carried out to identify (a) what circumstances hold men back from using cancer counseling services (CCS), even though they could profit from them, and (b) what contexts would help men to overcome such barriers (8, 15, 20–22). The findings informed a package of measures that were revised by focus groups comprising patients, physicians, and counselors and then piloted in one region of Germany (23). Based on the findings of this pilot study, the package was evaluated in the trial presented here. The principal study question was whether more men would use CCS if the male-specific package of measures were implemented in their local service’s catchment area.

The psychosocial outpatient cancer counseling offered by CCS covers, for example, provision of information about rights to healthcare services, psychoeducation, crisis intervention, social and psychological counseling, and referral to other healthcare services such as medical rehabilitation, psychotherapy, and palliative services (7, 24). CCS thus provide specific care for cancer patients, their relatives and friends (25).

**Method**

**Study design**

This article fulfills the stipulations of the CONSORT Statement extension for cluster-randomized trials. Our motivation for choosing the cluster-randomized trial design was that the measures related predominantly to structures and supraindividual processes. For this reason, we did not look at individual CCS, but rather examined regions as clusters. The measures were implemented in the intervention arm, while in the control arm work continued as before. After 12 months the numbers of persons seeking counseling from the CCS were compared between the intervention arm and the control arm. The randomization was carried out at the Interdisciplinary Center for Clinical Trials Mainz in the ratio 1:1, non-stratified. The ethics committee of the Rhineland–Palatinate Medical Association approved the trial (2019–14549). Registration of the trial took place after completion of data acquisition. We had initially attempted to register it with clinicaltrials.gov, but were refused. The associated correspondence led to delayed inclusion in the German Clinical Trials Registry, where the trial has been registered under DRKS00032181 since 4 July 2023.

**Sample**

Inclusion criteria: Catchment areas of outpatient CCS that meet the quality criteria of the German clinical practice guideline on psycho-oncology (28). The CCS were approached via the Cancer Counseling Service Committee of the German Cancer Society’s Psycho-Oncology Working Group. Most of the participating CCS had already been involved in previous joint research (8, 15, 20–22, 25). Exclusion criteria: Counseling services not dedicated to cancer; inpatient psycho-oncological services; university hospital outpatient departments.

Table 1

Characteristics of the sample (n = 6004)

First contacts in intervention phase		Control arm (n = 3295)		Intervention arm (n = 2709)	
		n	%	n	%
Sex	Male	848	26	832	31
	Female	2447	74	1877	69
Age in years	Median (min–max)	2858	56 (16–95)	2326	57 (16–95)
Marital status	Married/cohabiting	1488	45	1349	50
	Single	484	15	306	12
	Separated	320	10	226	8
	Widowed	172	5	125	5
	No data	831	25	703	26
Main tumor site	Breast & gynecological cancers	1105	34	905	33
	Gastrointestinal tract	448	14	355	13
	Hematological cancer	255	8	239	9
	Respiratory organs	256	8	203	8
	Central nervous system or eye	166	5	173	6
	Prostate and male genitalia	137	4	224	8
	Efferent urinary tract	92	3	67	2
	Head and neck	59	2	52	2
	Skin	74	2	66	2
	Other sites	193	6	160	6
	No data	510	16	265	10

**Endpoints**

The primary endpoint was the number of men who visited a CCS for the first time within 12 months (initial contact). Initial contact was defined as the first contact by a person (≥ 16 years old) with the CCS by telephone, in person, or by video. Contact-related approaches (e.g., telephone calls to make appointments), written advice, contacts that were not actively initiated by those seeking counseling (e.g., counseling in hospices), and contacts with experts seeking advice for professional reasons were excluded.

The secondary endpoint was the proportion of all contacts (initial contacts and any subsequent contacts) made up by men. This endpoint took account of how long the men remained in the counseling process.

**Intervention**

The extensive package of measures has been published (23) and will be described only briefly here. The measures applied at four different levels:

- Provision to referring professionals of information on the role of active recommendation of cancer counseling specifically to men.
- Targeting of men in publicity campaigns (e.g., by means of posters and short films).
- Structural changes in the counseling services (e.g., introducing evening appointments).

- Activities that bring men together and provide an informal space for conversations (e.g., sailing). The counseling services in the intervention arm all received the same professionally designed materials. Attention was consistently paid to lowering the barriers for men without raising those for women.

Online meetings took place every month to supervise implementation of the measures and promote exchange between the counseling services. The intervention phase began on 1 June 2021 and ended on 31 May 2022.

**Data acquisition and statistical analysis**

All endpoints were extracted from the routine CCS documentation. For analysis of the primary endpoint, the number of first contacts by persons seeking counseling per phase (reference period versus intervention phase) was modeled as a binomial parameter, and a logistic model with random effects adjusted for correlated data at cluster level and at cluster–period level was constructed. The model contained a fixed intervention effect for the intervention period and a period effect. In this way the proportion of men in the intervention year, adjusted for the proportion in the reference year, was compared between the arms. The intervention effect is expressed as odds ratio (OR) with 95% confidence interval [95% CI] (*eMethods*).

Table 2

Types of initial contact (n = 6004)

Initial contacts in intervention phase		Control arm (n = 3295)		Intervention arm (n = 2709)	
		n	%	n	%
Counseling setting	One-to-one counseling	2936	89	2507	93
	Couple/two-person counseling	136	4	180	7
	More than two persons	39	1	22	1
	No data	184	6	0	0
Status of person seeking counseling	Patient themselves	2226	68	2013	74
	Partner	413	13	358	13
	Other relative/friend	611	19	335	12
	Interested person	25	1	3	0
	No data	20	1	0	0
Type of counseling	Telephone	1858	56	1801	67
	Face to face	1134	34	902	33
	Video counseling	116	4	6	0
	No data	187	6	0	0

Results

Characteristics of the cancer counseling services

A total of 12 regions (13 CCS, two of them in a cluster) were randomized (Figure). The CCS were located in Saxony, Hamburg, Lower Saxony, North Rhine–Westphalia, Hesse, Baden–Württemberg, and Bavaria. The populations of the communities where the CCS were located varied from 16 380 to about 2 million.

The number of staff members per CCS ranged from 3 to 14 (2–12 working as counselors; on average, 5 in the intervention arm and 6 in the control arm). The total number of hours worked per week by all the staff at a CCS varied from 44 to 298 hours (130 hours on average overall; 104 in the intervention arm and 152 in the control arm). The average proportion of men among the counselors was 12% (6% in the intervention arm and 16% in the control arm). The total weekly working time was 118 hours for female counselors and 12 hours for male counselors.

Twelve of the 13 CCS had outposts: these ranged from 1 to 13 in number, were located 2–120 km from the hub, and in most cases were open once a week or once every two weeks.

Number of counseling sessions

A total of 1 986 persons were counseled for the first time (initial contacts), with 5982 of these first sessions taking place in the reference period (the 12 months before the intervention) and 6004 during the intervention phase. Table 1 shows the characteristics of those who sought counseling in the latter period. The majority of the initial contacts were one-to-one counseling sessions for the patients themselves (Table 2).

The grand total of counseling sessions (first and subsequent contacts) was 51 842, of which 25 191 took place in

the reference period and 26 651 during the intervention phase.

Primary endpoint: proportion of men among the initial contacts

In the reference period, 2689 initial counseling sessions were conducted in the CCS of the intervention arm (proportion of men: 30.2%) and 3293 in the CCS of the control arm (proportion of men: 26.4%) (Figure, Table 3).

During the intervention phase, 2709 initial counseling sessions were conducted in the intervention arm (proportion of men: 30.7%) and 3295 in the control arm (proportion of men: 25.7%).

Therefore, there was:

- A difference of 5% in the proportion of men between the intervention arm and the control arm during the intervention phase.
- An increase of 0.5% in the proportion of men in the CCS of the intervention arm from the reference period to the intervention phase, while in the CCS of the control arm the proportion of men decreased by 0.7%.

Taking the data structure into account, the proportion of men was 3.3% higher in the intervention arm than in the control arm. This corresponded to a model-based adjusted OR of 1.2 [1.0; 1.4]; p = 0.08. In a sensitivity analysis, the months before the reference period (1 January to 31 May 2020) were included: the intervention effect and the p-value remained unchanged.

Secondary endpoint: proportion of men among all contacts (initial and subsequent contacts)

In the reference period, 10 337 counseling sessions were conducted in the intervention arm (proportion of men: 26.5%) and 14 854 in the control arm (proportion of men:

Table 3

The proportion of men among those visiting the cancer counseling services (CCS) during the reference period and the intervention phase

		Initial contacts			Initial and subsequent contacts		
		Before the intervention	During the intervention	Difference	Before the intervention	During the intervention	Difference
Intervention	CCS a	22.8%	30.4%	7.6	21.2%	29.0%	7.8
	CCS b	21.8%	29.1%	7.3	17.3%	27.0%	9.7
	CCS c	37.1%	36.8%	-0.3	25.1%	30.4%	5.3
	CCS d	35.5%	34.1%	-1.4	36.9%	31.9%	-5.0
	CCS e	30.5%	28.3%	-2.2	25.5%	23.8%	-1.7
	CCS f	26.7%	25.3%	-1.4	26.2%	28.6%	2.4
	<b>Overall</b>	<b>30.2%</b>	<b>30.7%</b>	<b>0.5</b>	<b>26.5%</b>	<b>27.6%</b>	<b>1.1</b>
Control	CCS a	23.9%	25.9%	2.0	22.6%	25.1%	2.5
	CCS b	30.8%	20.3%	-10.5	27.0%	22.4%	-4.6
	CCS c	27.0%	23.3%	-3.7	27.9%	20.2%	-7.7
	CCS d	30.0%	27.8%	-2.2	18.7%	21.5%	2.8
	CCS e	24.9%	28.2%	3.3	19.3%	23.0%	3.7
	CCS f	25.7%	23.7%	-2.0	26.8%	23.8%	-3.0
	CCS g	29.9%	28.5%	-1.4	19.8%	20.0%	0.2
	<b>Overall</b>	<b>26.4%</b>	<b>25.7%</b>	<b>-0.7</b>	<b>22.2%</b>	<b>22.2%</b>	<b>0.0</b>

22.2%) (Table 3). During the intervention phase, 11 681 counseling sessions were conducted in the intervention arm (proportion of men: 27.6%) and 14 970 in the control arm (proportion of men: 22.2%). Therefore, there was:

- A difference of 5.4% in the proportion of men between the intervention arm and the control arm during the intervention phase
- An increase of 1.1% in the proportion of men in the CCS of the intervention arm from the reference period to the intervention phase, while in the CCS of the control arm the proportion of men remained constant.

The adjusted OR was 1.3 [1.1; 1.6]; p = 0.01.

### Discussion

An estimated 2 129 300 men in Germany are living with cancer (27). Working on the assumption that 30% of them are experiencing psychosocial stress and at least sometimes require professional support (9, 28), this means 638 790 men need help. A broad spectrum of healthcare services is now available to these men (30) and can be accessed free of charge (24), albeit not always quickly or close to where they live (29, 30). Therefore, barriers to use are not exclusively related to the absence of suitable healthcare options (31); rather, they arise from other factors that are modifiable. This was our study's point of departure.

Our hypothesis was that by means of a package of targeted measures we would be able to raise the proportion of initial contacts made up by men from 30% to 36%, corresponding to an OR of 1.3. Ultimately, however, the OR was 1.2, lower than expected. Moreover, the strength of the

intervention effect varied among the individual CCS. The reason for this may have been random fluctuations or genuine variation in the impact of the measures. The latter could on one hand be related to regional differences in implementation of the measures, or on the other hand to differences in the way the populations of the regions reacted to the measures. On the basis of the documentation relating to the efforts made to implement the measures, we can state that there was no simple linear relationship between the time invested and the intervention effect at the CCS level.

If all contacts are considered together, i.e., first as well as subsequent contacts, the package of measures led to an even greater increase in the proportion of men (OR 1.3). Not only the number of men who visited a counseling service (for the first time) played a role, but also how long they remained in counseling. It should be noted in this regard that longer counseling processes are not necessarily better: a small number of conversations may suffice to achieve a successful counseling result (32, 33). When a lengthier counseling process is necessary to attain a good outcome, however, it is essential that the person seeking counseling does not break off contact prematurely. This finding thus has practical relevance.

One limitation that should be mentioned is that the pilot and intervention phases coincided with the beginning of the COVID-19 pandemic. The CCS were therefore affected by changes that had nothing to do with the intervention. Because the pandemic affected all of the CCS in the same way, however, the results of the trial should not be compromised.



A further critical aspect is the adaptation of the package of measures to local conditions. This was planned and is considered a core characteristic of complex interventions (34, 35); however, it led to variation of the intervention among clusters (in Essen, for instance, the male-specific option was a sailing group, whereas in Münster it was hiking). This increases the variance of the data and reduces the internal validity of the results, but augments their external validity.

It also has to be taken into account that we planned to increase the proportion of men seeking counseling without reducing CCS attendance by women. The package of measures was explicitly constructed with this in mind. The strengths of the trial include the randomized study design and the large number of cases. A further plus point is that we did not rely on self-assessment but used documented healthcare data for analysis. The results could probably be accurately extrapolated to other regions, because both rural and urban areas were included. However, the eastern part of Germany was underrepresented, with only one region.

Finally, it must be noted that implementation of the measures, though manageable, involved considerable time and effort. For this reason, the CCS in the intervention arm each received € 5000. However, this sum did not cover the costs. All of the CCS documented the time required for implementation of the measures, which amounted on average to 303 hours. Assuming an hourly rate of € 50 yields a total cost of over € 15 000. This calculation does not include the working time for the trial itself (exporting the routine data, taking part in trial meetings, etc.). Each CCS received a sum of € 700 for the time and effort invested in documentation.

The results show that implementation of the measures (23) at various levels can increase the proportion of men using outpatient cancer counseling services. The effect is not large, but considering the relatively short period for which the measures were applied (1 year), it is relevant for healthcare practice. Our findings underline the experience gained from other projects, i.e., that men's hesitation to take up offers of psychosocial assistance cannot easily be overcome. Some men seem to have internalized the attitude that it is not manly to accept help and fear shaming should they do so (36, 37). One can work on changing these perceptions, but it may take years, and cancer often requires swift support. Our approach was therefore geared to making it easier for men to access CCS despite the possible presence of these worries. To achieve this, men need to be addressed directly and "fetched," perhaps even literally (8, 38). In the above-mentioned program in Edmonton, for example, the men were picked up every week by bus from their accommodation (hostels for the homeless). In relation to CCS, the "fetching" consists, for instance, of the physician taking seriously any concerns the patient may have (22, 39) and attempting to counter them by providing information about the content and process of counseling or even, if so desired, arranging a CCS appointment jointly with the person seeking advice.

The package of measures can now be implemented elsewhere (materials available [in German] at [www.gutgenkopfkino.de/](http://www.gutgenkopfkino.de/)). We recommend continued evaluation.

**Data sharing**

The original data are available in aggregated form on reasonable request, provided the cancer counseling service concerned permits use of its data for the stated purpose.

**Funding**

The study was funded by German Cancer Aid (project number: 70113528). Study registration number: DRKS00032181. Study title: "Wege ebnen für Männer – Geschlechtsspezifische Zuweisung und Konzepte für die ambulante Krebsberatung" (WAG-ES!) [Paving the way for men—sex-specific referral and concepts for outpatient cancer counseling].

**Conflict of interest statement**

SS receives consultancy fees annually from Lilly in the context of the Lilly Quality of Life Award.

The remaining authors declare that no conflict of interest exists.

Manuscript received on 22 September 2023, revised version accepted on 10 January 2024.

Translated from the original German by David Roseveare.

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#### Cite this as:

Singer S, Wunsch A, Ihrig A, Bruns G, Holz F, Jakob J, Bessler M, Engesser D, Blettner M, König J, Bayer O: Men's access to outpatient psychosocial cancer counseling—a cluster-randomized trial. *Dtsch Arztebl Int* 2024; 121: 121–7. DOI: 10.3238/arztebl.m2024.0005

#### Supplementary material

For eReferences please refer to:

[www.aerzteblatt-international.de/m2023.0005](http://www.aerzteblatt-international.de/m2023.0005)

Supplementary material to accompany the article:

## Men's Access to Outpatient Psychosocial Cancer Counseling

A Cluster-Randomized Trial

by Susanne Singer, Alexander Wünsch, Andreas Ihrig, Gudrun Bruns, Franziska Holz, Johannes Jakob, Markus Bessler, Deborah Engesser, Maria Blettner, Jochem König, and Oliver Bayer

Dtsch Arztebl Int 2024; 121: 121–7. DOI: 10.3238/arztebl.m2024.0005

### eMETHODS

#### Data acquisition

All endpoints were extracted from the counseling services' routine documentation. Therefore, the persons seeking counseling were not asked for a statement of consent.

Because the counseling services used four different documentation systems (TIKANIS, freinet, and two self-compiled databases, one on the basis of Access, the other based on KB-Eos/MSSQL), which were also modified during the trial period, we defined a core set of variables to be documented uniformly by all counseling services. In some cases this necessitated adjustment of the documentation procedures.

All contacts during the period from 1 January 2020 to 31 May 2022 were exported. Data from the 12 months preceding the intervention phase (reference period: 1 June 2020 to 31 May 2021) and from the intervention phase (1 June 2021 to 31 May 2022) were analyzed.

The following parameters were documented for each contact: age and sex of person seeking counseling, type of contact (initial or subsequent contact), status (patient, relative/friend), type of counseling (face to face, telephone, online), date, and setting (one to one, two or more persons).

The following characteristics of the CCS were recorded: federal state and population of the city where the service is located; outposts of the CCS (number, distance from hub, opening times); number, qualification, and sex of counselors.

#### Statistical analysis

The characteristics of the CCS and of the persons seeking counseling for the first time (during the intervention phase) were described. It should be noted that the number of first contacts does not correspond precisely

with the number of persons visiting the CCS, because contacts following on from previous counseling sessions could take place during the intervention phase.

For analysis of the primary endpoint, the number of initial contacts by men seeking counseling was modeled as a binomial parameter by phase (reference period versus intervention phase) and a logistic model with random effects adjusted for correlated data at cluster level and cluster-period level was constructed. This model contained a fixed intervention effect for the intervention period and a period effect. In this way the proportion of men in the intervention year, adjusted for the proportion in the reference year, was compared between the arms. The intervention effect is expressed as odds ratio (OR) with 95% confidence interval (CI).

For the secondary endpoint (initial and subsequent contacts), the procedure was as follows: First, all contacts in the intervention phase made by persons who had already had contacts in the period preceding intervention were discarded. Next, the numbers of initial and subsequent contacts per cluster were added together, separately for males and females, and analyzed as a negative binomial distribution parameter in a suitable generalized mixed model. The intervention effect is also expressed as OR with 95% CI and shows up as a contrast registering the shift in contacts towards men seeking counseling in the intervention phase. Data analysis of the endpoints was carried out using SAS, version 9.4; the statistician was not blinded to the intervention status of the CCS. The characteristics of the CCS were analyzed by a different person using STATA, version 15.0. This person was blinded to the allocation (intervention group versus control group).