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NEW STUDY

The INTERPHONE study: design, epidemiological methods, and description of the study population

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Abstract The very rapid worldwide increase in mobile phone use in the last decade has generated considerable interest in the possible health effects of exposure to radio frequency (RF) fields. A multinational case–control study, INTERPHONE, was set-up to investigate whether mobile phone use increases the risk of cancer and, more specifi-

Baruch Modan is deceased.

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cally, whether the RF fields emitted by mobile phones are carcinogenic. The study focused on tumours arising in the tissues most exposed to RF fields from mobile phones: glioma, meningioma, acoustic neurinoma and parotid gland tumours. In addition to a detailed history of mobile phone use, information was collected on a number of known and potential risk factors for these tumours. The study was conducted in 13 countries. Australia, Canada, Denmark, Finland, France, Germany, Israel, Italy, Japan, New Zealand, Norway, Sweden, and the UK using a common core protocol. This paper describes the study design and methods and the main characteristics of the study population. INTERPHONE is the largest case–control study to date investigating risks related to mobile phone use and to other potential risk factors for the tumours of interest and includes 2,765 glioma, 2,425 meningioma, 1,121 acoustic neurinoma, 109 malignant parotid gland tumour cases and 7,658 controls. Particular attention was paid to estimating the amount and direction of potential recall and participation biases and their impact on the study results.

Keywords Mobile phones · Case–control · Methods · Study design · Cancer · Benign tumours · Brain tumours · Acoustic neurinoma · Parotid gland tumours

Abbreviations

CAPI	Computer assisted personal interview
CT	Computed tomography
ELF	Extremely low frequency
EMF	Electro-magnetic fields
ICNIRP	International Commission on Non-Ionizing Radiation Protection
MRI	Magnetic resonance imaging
SAR	Specific absorption rate
SES	Socio-economic status
UK	United Kingdom

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Introduction

It is estimated that there are now over 2 billion mobile phone users in the world, and this number continues to increase [1]. Widespread concern that exposure to RF fields emitted by mobile phones may have an impact on health has accompanied the dramatic increase in use of these phones worldwide [2].

In the late 1990's, several expert groups critically reviewed the available evidence concerning the possible health effects of low-level exposures to RF fields and recommended that research be carried out to determine whether mobile (also called cellular) phones could cause adverse health effects [3–6].

As a result, a feasibility study was carried out in fourteen countries, coordinated by the International Agency for Research on Cancer (IARC) in Lyon. It was concluded that an international study of the relation between mobile phone use and risk of adult head and neck tumours, including brain tumours, would be both feasible and informative [7], while studies of these relatively rare tumours in single countries would generally lack sufficient statistical power. Thus INTERPHONE was initiated as a set of multi-national case–control studies, focusing on four types of tumour: glioma, meningioma, acoustic neurinoma and parotid gland tumours.

Since the beginning of INTERPHONE, the results of a number of other studies on the risk of head and neck tumours in relation to mobile phone use have been published. These include both cohort and case–control studies [8–16]. To date, however, the evidence remains inconclusive about a possible association between mobile phone use and the risk of cancer.

The current paper presents the design, detailed methods, and description of the study population in all the participating centres of INTERPHONE. Some of these centres have already published results [17–38].

Separate papers, based on the full international INTERPHONE study, will address (1) the possible relationship between the risk of these tumours and mobile phone use; (2) the possible relationship between the risk of these tumours and estimated RF exposure from mobile phone use; (3) the contributions to tumour risk of other possible risk factors.

Objectives

The primary objective of INTERPHONE was to investigate whether mobile phone use increases the risk of tumours and, specifically, whether RF fields emitted by mobile phones are tumourigenic.

Most of the RF absorbed energy from mobile phone use is absorbed in the immediate vicinity of the handset, in a volume of about 5 cm^3 in the head. Of this, most is absorbed by the skin, the salivary glands (particularly the parotid gland) and the external ear; only 20–30% is absorbed by the brain as a whole [39]. In the brain, absorbed energy is highest for glial and meningeal tissue located in the outermost part of the frontal, parietal and temporal lobes on the side of the head where the phone is used [39–41]. The tumour types selected for study are those that occur in some of the tissues that receive most of the RF exposure from mobile phone use.

A secondary objective was to evaluate the relation between these tumours and a number of known and potential risk factors, including ionising radiation, occupational exposure to electromagnetic fields and the subject's personal and familial medical history.

Methods

Sixteen study centres in thirteen countries (Australia; Canada: Montreal, Ottawa, Vancouver; Denmark; Finland; France; Germany; Israel; Italy; Japan; New Zealand; Norway; Sweden; and the UK: North and South) participated in INTERPHONE.

Source population

In Australia, Canada, France, Germany, Italy, Japan and New Zealand, the source population was restricted to major metropolitan areas where mobile phones were first introduced (Table 1). Major treatment centres for the diseases of interest are concentrated in these areas and most of the population is unlikely to go out of the region for diagnosis and treatment. In all study regions except Paris and Tokyo, it is believed that 90 to 95% of the cases are diagnosed or treated in the collaborating units (Web Annex Table 1) in the study areas. For practical reasons, limiting the study area to these populations also facilitated face-to-face interviews. In Denmark, Finland, Israel, Norway and Sweden the study was largely nationwide. The UK-South study was restricted to the South East of England, urban and rural, and the UK-North study encompassed both urban areas and sparsely populated rural areas.

All residents in the study regions aged 30 to 59 were eligible for the study; additional eligibility criteria, such as citizenship and proficiency in the local language were imposed in some study centres (Web Annex Table 1). The choice of age-range aimed to maximise the likelihood of exposure. Mobile phone use is a relatively new phenomenon: until the late 1990's mobile phone use was mainly

Table 1 Definitions of the study regions and sizes of the source populations

Study centre	Definition of study regions	Size of the source population—age 30–59 (in thousands)	Source population	Source of controls
Australia	Sydney Statistical Division	M = 825; F = 839; Total 1,664	Citizens resident in the study regions, capable of participating in a face-to-face interview in English.	Electoral lists
	Melbourne Statistical Division	M = 691; F = 720; Total 1,411		
Canada	Greater Metropolitan Montreal	M = 755; F = 784; Total 1,539	Citizens resident in the study regions	Electoral lists
	Ottawa, Eastern Ontario and Ottawa Valley	M = 267; F = 276; Total 543	Residents of the study region	Random digit dialling
	Vancouver, Lower BC Mainland, Greater Victoria area of Vancouver Island	M = 607; F = 619; Total 1,226	Residents of the study region	The population-based BC Ministry of Health Client Registry
Denmark	Denmark without Greenland and Faroe Islands	M = 1,069; F = 1,041; Total 2,200	Residents of the study region who speak Danish and have no previous history of cancer (excluding benign skin tumours)	Central Population Registry
Finland	All Finland, excluding Åland and northernmost Lapland (source population covers 98.5% of population)	M = 1,134; F = 1,109; Total 2,243	Residents of the study region	Central Population Registry
France	Metropolitan region of Lyon	M = 232; F = 240; Total 472	Citizens resident in the study regions	Electoral lists
	Metropolitan region of Paris – Ile de France	M = 2,320; F = 2,391; Total 4,711		
Germany	Bielefeld: 5 "Kreise" (a German administrative unit similar to a county) Heidelberg: 18 "Kreise" Mainz: 10 "Kreise"	M = 1,440; F = 1,427; Total 2,867	Residents of the three study regions with sufficient knowledge of the German language to undertake the interview	Regional population registries
Israel	The entire Jewish population within Israel	M = 863; F = 909; Total 1,772	Jewish citizens of Israel.	National Population Registry
Italy	Municipality of Rome	M = 622; F = 652; Total 1,274	Residents of Rome.	Population Registry of the Municipality of Rome
Japan	Tokyo (23 wards and 14 cities); the adjacent 25 districts of Saitama, Chiba and Kanagawa	M = 4,772; F = 4,478; Total 9,250	Residents of the study region	Random digit dialling
New Zealand	Greater Auckland; Hamilton, Rotorua, Tauranga; Napier, Hastings; Wellington, Palmerston North; Christchurch	M = 440; F = 460; Total 900	Residents of the study regions for at least 6 months	Electoral rolls
Norway	All of Norway south of Nordland county, except the less populated area served by Troms Hospital in the north	M = 1,287; F = 1,261; Total 2,548	Residents of the study regions	Population registry
Sweden	Four regions (Stockholm, Göteborg, Lund/Malmö, Umeå) which covers approximately 2/3 of the country. In the northern region, only the more densely populated areas are included	M = 1,220; F = 1,180; Total: 2,400	Residents of the study regions, able to understand Swedish, and not completely deaf prior to diagnosis or reference date	Population registry

Table 1 continued

Study centre	Definition of study regions	Size of the source population—age 30–59 (in thousands)	Source population	Source of controls
UK-North	Central Scotland (Lothian, Fife, Forth Valley, Greater Glasgow and Lanarkshire, Ayrshire and Arran), West Yorkshire, Trent, West Midlands, containing both densely populated urban city conurbations and sparsely populated rural areas	M = 3,132; F = 3,206; Total 6,338	Residents of the study regions	General practice patient lists
UK-South	The 'Thames regions' of South east England, comprised of Greater London and surrounding counties. It is both urban and rural	M = 2,685; F = 2,780; Total 5,465	Residents of the study region	General practice patient lists

restricted to people in the age range most likely to use the phones for business purposes [7].

Case eligibility and ascertainment

Eligible cases were all residents of the study region diagnosed during the study period with a confirmed first primary glioma, meningioma, or acoustic neurinoma. Eight centres (Australia; Canada—Montreal, Ottawa and Vancouver; Denmark; Israel; Italy; Sweden) also included malignant parotid gland tumours. Because benign parotid gland tumours may be treated in a very large number of institutions, most centres found it logistically difficult to ensure complete ascertainment, and only Canada–Ottawa, Israel and Sweden included them. They will not be discussed in this paper. The ICD codes for the eligible diagnoses are presented in Web Annex Table 2.

All diagnoses were either histologically confirmed or based on unequivocal diagnostic imaging. In Australia and Germany, only histologically confirmed tumours were included. In Denmark cases found to have had any previous cancer (excluding non-melanocytic skin cancer) were excluded.

Each centre established procedures for the rapid ascertainment of cases from participating diagnostic and treatment units, which was particularly important for glioma patients, whose health can deteriorate quickly. Every effort was made to maintain a close relationship with the units to ensure that cases were not missed and that the required authorisations were obtained from treating physicians when necessary. Close monitoring of case ascertainment was essential and all study centres, except Finland and Japan, used one or more secondary source (including medical archives, hospital discharge and billing files, and hospital or regional cancer registries) to improve ascertainment levels. Enrolment of cases through secondary sources often implied longer delays in case ascertainment and consequently lower participation.

Control eligibility and selection

Controls were randomly selected from the source population. The sampling frame depended on the local situation (Table 1). The study design called for controls to be individually- or frequency-matched to cases, with the number of controls varying according to the tumour type: 1 control per case for brain tumours; 2 for acoustic neurinoma; and 3 for parotid gland tumours. In Germany, two controls were selected for each brain tumour case. Controls were matched on year of birth (within 5-year categories), sex and study region.

Controls were individually matched to cases in Canada–Ottawa, Vancouver; France, Israel, Japan, New Zealand

and UK-North. In the other centres, individual matching was conducted post hoc, with cases being assigned controls chosen to have been interviewed as close as possible in time to the case, from among those who fit the matching criteria.

Approach to subjects and informed consent

All cases for whom physician authorisation for contact had been obtained and all controls were initially informed about the study and asked to participate. The procedures varied between centres (Web Annex Table 3), depending on the requirements of local Ethics Review Boards. In seven centres, the cases were initially approached by the treating physician or a nurse for consent to be included in the study. In other study centres approaches included: active case ascertainment by the study staff followed by physician authorisation to contact each case directly; blanket approval to contact all eligible cases; or a mix of the two. In all centres participants provided signed informed consent.

Collection of information on individual study subjects

Whenever possible, consenting subjects were interviewed face-to-face by trained interviewers using a computer-assisted personal interview (CAPI) questionnaire. Only Finland used a paper version of the questionnaire. In exceptional cases, telephone interviews were conducted with difficult-to-reach subjects. If subjects became too tired or confused to complete the interview in one session a second appointment was arranged; a partner or other family member could assist in the interview. When the study subject had died or was too ill to participate, a proxy respondent was interviewed where this was possible and permitted by ethics committees. In Australia and New Zealand an abbreviated questionnaire was used for proxy interviews. Controls who refused to participate in the study were asked, whenever possible, to complete a short non-respondent questionnaire in all centres, except in Denmark and UK-South, in order to evaluate whether they differed from participating controls. A small number of cases in some centres also completed the non-respondent questionnaire. Detailed results of analyses of the non-respondent questionnaires will be published separately.

The study questionnaire covered demographic factors, mobile phone use (detailed below), use of other wireless communication devices including cordless DECT telephones, occupational exposures to EMF and other potential confounders or risk factors for the diseases of interest (including exposure to ionising radiation, smoking and the subject's personal and familial medical history). Specific questions on exposure to loud noise and hearing loss were asked of acoustic neurinoma cases and their controls (and of all controls in centres using frequency matching).

History of mobile phone use

Detailed questions were asked of regular mobile phone users, defined as those with an average of at least one call per week for a period of 6 months or more, concerning their history of phone use. A paper calendar was handed to the subject. Together, the respondent and interviewer attempted to identify each phone used (aided by show cards with pictures of hundreds of models of mobile phones that were compiled and updated during the course of the study) and to reconstruct the time period during which it was used. This provided the subject with a visual record of the phone history when responding to the subsequent detailed questions.

For each phone, detailed questions were asked about the initial pattern of use, including network operator and average number and duration of calls, and any subsequent changes in use patterns. Questions were also asked about the proportion of time the phones were used in urban, suburban or rural settings, while stationary or moving in a vehicle, how often the antenna was extended, and whether headsets or hands-free kits were used, as these factors may modify the RF output power of the phones. The side of the head on which the phone was usually held (i.e. the laterality of phone use) and the handedness (left or right-handed) of the subject were recorded.

Validation studies

Validation studies were conducted to assess the accuracy of subjects' recall of their history of mobile phone use. Short-term recall was assessed in volunteer subjects using either software modified phones or network operators' records in eleven countries [42]. Validation of medium- to long-term recall of phone use in comparison with network operator records was possible in three countries (Australia, Canada and Italy) for cases and controls, while validation of short-term recall was possible for some subjects in Denmark, Israel, and Sweden. Detailed methods and results of these studies will be published separately.

Information on socio-economic status (SES) and other socio-demographic factors

Attained level of education was used as a proxy for SES. As education systems and attained levels do not have a direct correspondence from one country to another, country-specific options for responses were used and recoded into one of two schemes as indicated in Web Annex Table 6. The exception was Germany, where an algorithm

developed by the German Epidemiological Association was applied [43]. Marital status and, where appropriate, education level of the spouse were also recorded.

Diagnostic information

Detailed diagnostic information was obtained from medical records for all cases interviewed and for non-interviewed cases in most study centres. This information included anatomical location and side of the tumour and histopathology, including whether benign, malignant or of uncertain behaviour (Web Annex Table 2).

Localisation of brain tumours

Since intracranial RF energy deposition from mobile phones is non-uniform, with most of the energy absorbed in the vicinity of the phone, the probable location of the origin of the brain tumours was identified so that the RF "exposure" at that location could be evaluated. Neuro-radiologists in each centre reviewed radiological images (MRI and CT scans) or records and recorded tumour location on a generic 3-dimensional grid map of the human head, made up of cubes 1 cm^3 in size, which was developed for the purpose. The details of this methodology will be published separately.

Data quality assurance

The CAPI questionnaire included many checks: the sequence of questions was constrained with little opportunity to skip questions and automatic range and consistency checks were incorporated. After completion of the interviews, routine checks were performed on the data from all centres both locally and centrally. Inconsistencies and ambiguities were identified and resolved wherever possible.

Assessment of exposure from mobile phones

The study used two main approaches to characterising exposure from mobile phones. The first depended only on the history of use derived from questionnaire responses and the second attempted to evaluate the amount of RF energy absorbed in different areas of the brain.

In both approaches, exposure was calculated up to a given reference date, which was set to the date of the diagnosis of the case in each matched set. Evaluation of RF energy absorption required the localisation of the tumour, which was defined crudely in terms of the side of the head, or lobe of the brain, or more precisely, from the exact location of the tumour on the 3-dimensional grid. Exposure for each control was estimated at the location of the tumour of his/her matched case.

Exposure derived from mobile phone history

Indices of exposure, including cumulative call time, average call duration and cumulative number of calls, overall and within specific time-windows, with and without use of hands-free devices, were computed using the detailed information reported by regular users.

Absorbed RF energy

The amount and distribution of RF energy absorption in the head vary according to a number of factors, including the type of telephone and network (frequency and type of transmission: digital or analogue, continuous or discontinuous, use of power control), as well as the subject's patterns of use of the phone. We developed and validated a model to estimate exposure, assessing the relative importance of the different factors and testing the adequacy of the proposed approach. The algorithm combines questionnaire responses with information on tumour location, the distribution of the specific absorption rate (SAR) of RF in the head and factors that modify the amount of RF energy emitted by the phone. This will be the subject of a separate paper.

Missing data

To avoid exclusion of subjects with missing responses to questions about mobile phone use (which might be more frequent in cases and long-term users and hence lead to a bias), rules were developed for the imputation of missing data. Hierarchical rules were defined a priori, and the same imputation procedure was applied to each pertinent instance. For example, if the number or duration of calls made during a specific time period was missing, but the subject provided information for adjacent time periods, the value was imputed as the average of the two adjacent periods. When this information was not available, the imputed value was the median use of all other users, in the same period and region [44, 45].

Analytical methods

The primary goals of the international analyses are to assess whether use of mobile phones and exposure to RF fields increase the risk of selected tumours. In devising analytic strategies, the following features must be considered:

- Exposure (absorbed RF energy from the phone) is highly localised;
- The prevalence of phone use has increased rapidly during the course of the study;

- If there is risk, most previous studies imply that it would be of low magnitude on the relative risk scale;
- The mechanism for an effect, if there is one, is unknown; the relevant exposure metric is therefore uncertain.

The main analyses will be based on conditional logistic regression for matched sets. This simplifies the assignment of the reference date, laterality and "tumour location" for the controls, which are important when analysing the effects of an exposure that is very localised. In addition, for an exposure that increased rapidly during the course of the study, and considering that subjects' recall of their past exposures may be influenced by their current and recent use patterns, the matching ensures that cases and controls have been interviewed relatively closely in time.

Results

Case ascertainment

The median delay between date of diagnosis and interview for glioma cases was 3 months, ranging from less than 2 months in three centres to 14 months in Norway where initial difficulties in the identification of cases were only overcome at a later stage (Table 2). Delays for meningioma were similar overall (not shown), although the median in several centres was a little longer than for glioma. Delays for acoustic neurinoma and malignant parotid gland tumours tended to be longer—overall median 6 months and 9 months respectively: because of their generally good prognosis, retrospective case ascertainment over a period of one year was allowed for these tumour types to increase the sample size.

The proportion of low to high-grade glioma cases ascertained was quite consistent across most centres where this could be determined: 66% high-grade and 28% low-grade, with 6% unknown overall. Overall 1% of the meningiomas were malignant and 5% of unknown behaviour. This was consistent across all study centres (not shown).

Control recruitment

Table 3 shows the distribution of intervals between the dates of interview of glioma cases and their matched controls. The overall median interval was 2 months, but varied by centre, ranging up to 6 months in Japan and 8 months in Israel. 72% of the controls were interviewed within 6 months of their matched cases. The proportions

Table 2 Distribution of delays between diagnosis and interview—glioma cases only

Study Centre	Number of cases	Delay between diagnosis and interview (months)				
		Median	Percentage of cases			
			–1 to 1	1 to 3	3 to 6	More than 6
Australia	301	4	1	41	30	29
Canada						
Montreal	65	7	0	3	37	60
Ottawa	25	8	8	16	8	68
Vancouver	80	5	0	1	60	39
Denmark	181	2	15	50	19	16
Finland	178	0	75	16	4	4
France	94	2	32	30	14	24
Germany	256	0	69	6	5	20
Israel	180	3	19	27	18	36
Italy	118	6	15	15	19	50
Japan	60	1	42	40	12	7
New Zealand	84	4	0	27	58	14
Norway	180	14	16	2	7	75
Sweden	227	3	13	42	30	15
UK						
North	429	2	5	62	20	13
South	307	4	2	27	34	37
Total	2,765	3	19	31	22	27

Table 3 Distribution of interval between the dates of interview of controls and of cases to which they are matched—glioma cases only

Study Centre	Number of cases[a]	Interval between interview of controls and date of interview of the cases to which they are matched (months)					
		Median	Percentage of matched sets				
			More than 6 months before case	1 to 6 months before case	Within 1 month of case	1 to 6 months after case	More than 6 months after case
Australia	297	0	11	10	35	28	16
Canada							
Montreal	65	0	9	20	46	25	0
Ottawa[b]	25	1	4	24	24	40	8
Vancouver[b]	80	3	1	6	17	51	24
Denmark	179	0	1	11	51	30	7
Finland	177	1	2	12	40	36	11
France[b]	94	4	1	0	6	60	33
Germany	256	3	11	10	9	48	22
Israel[b]	180	8	2	6	3	30	59
Italy	118	5	16	15	4	24	41
Japan[b]	60	6	0	2	2	47	50
New Zealand[b]	83	5	4	3	8	44	40
Norway	154	0	16	22	23	19	20
Sweden	222	1	3	14	31	34	18
UK							
North[b]	421	3	0	0	7	76	17
South	299	1	7	17	31	24	21
Total	2,710	2	6	10	21	41	23

[a] Only cases with matched controls are included

[b] Study centre with individual matching of controls to cases

were respectively 6% and 23% for interviews more than 6 months before, and more than 6 months after their matched cases. The former was very low (< = 4%) in the study centres where individual matching was used.

Participation

Case participation varied considerably by tumour type and by centre (Table 4). The overall participation was 65% for glioma cases (ranging from 37% to 92%), 78% for meningioma (ranging from 57% to 92%), 82% for acoustic neurinoma (ranging from 70% to 100%) and 75% for malignant parotid gland tumours (with a wide range based on very small numbers).

Participation was calculated as the proportion of all eligible ascertained cases that were interviewed. The denominator includes cases whose physician denied authorisation to contact them: 5% of glioma, 2% of meningioma and acoustic neurinoma and 9% of malignant parotid gland tumour cases. This proportion was relatively small for most centres and in eight centres there were none at all.

There was little difference between centres in participation of glioma cases according to grade of tumour: 67% overall for cases with high-grade tumours and 71% for cases with low-grade tumours.

Overall participation amongst controls was 53% (Table 4) but showed large variation across centres, ranging from 35% to 74%. Eight of the study centres achieved control participation of 60% or higher. The major reasons for non-participation were refusal (64% of non-participants) and inability to contact (27%).

Amongst cases there was very little difference in participation by age except in women with glioma, where participation in the older age group was noticeably lower. Amongst controls there were slightly higher participation rates amongst women than men (Table 5).

Type and location of interview

The vast majority of interviews (94% for glioma cases and 95% for controls) were conducted face-to-face; the remaining interviews were conducted by telephone (Table 6). In most centres the proportion of face-to-face

Table 4 Distribution of all cases and controls ascertained and proportion interviewed by study centre

Study centre	Glioma		Meningioma		Acoustic neurinoma		Malignant parotid gland tumours		Controls	
	No. ascertained	No. (%) Interviewed	No. ascertained	No. (%) interviewed	No. ascertained	No. (%) interviewed	No. ascertained	No. (%) interviewed	No. from sampling frame	No. (%) interviewed
Australia	536	301 (56)	413	255 (62)	179	127 (71)	21	7 (33)	1,608	669 (42)
Canada										
Montreal	101	65 (64)	71	48 (68)	41	33 (80)	13	9 (69)	391	234 (60)
Ottawa	38	25 (66)	18	15 (83)	21	17 (81)	6	6 (100)	259	180 (69)
Vancouver	134	80 (61)	45	31 (69)	41	34 (83)	19	13 (68)	680	239 (35)
Denmark	248	181 (73)	155	121 (81)	73	71 (97)	15	15 (100)	1,277	662 (52)
Finland	211	178 (84)	252	231 (92)	87	76 (87)	–[a]	–	1,337	559 (42)
France	155	94 (61)	190	148 (78)	140	111 (79)	–	–	639	472 (74)
Germany	312	256 (82)	275	250 (91)	76	67 (88)	–	–	1,869	1190 (64)
Israel	206	180 (87)	390	350 (90)	78	72 (92)	20	19 (95)	911	599 (66)
Italy	128	118 (92)	124	110 (89)	30	30 (100)	11	11 (100)	486	340 (70)
Japan	90	60 (67)	102	82 (80)	82	69 (84)	–	–	568	287 (51)
New Zealand	132	84 (69)	72	54 (75)	21	20 (95)	–	–	350	172 (49)
Norway	236	180 (76)	191	148 (77)	51	38 (75)	21	11 (52)	404	278 (69)
Sweden	298	227 (76)	205	184 (90)	107	102 (95)	20	18 (90)	617	407 (66)
UK										
North	628	429 (68)	222	180 (81)	116	102 (88)	–	–	1,747	788 (45)
South	848	307 (37)	390	221 (57)	218	152 (70)	–	–	1,211	582 (48)
Total	4,301	2,765 (65)	3,115	2,425 (78)	1,361	1,121 (82)	146	109 (75)	14,354	7,658 (53)

[a] Parotid gland tumours were not included in these centres

Table 5 Participation rates amongst cases and controls by age and sex, all study centres combined

Number of cases ascertained and controls selected (% interviewed)										
Age	Glioma		Meningioma		Acoustic neurinoma		Malignant parotid gland tumours		Controls	
	Women	Men	Women	Men	Women	Men	Women	Men	Women	Men
30–39[a]	398 (70)	565 (67)	313 (74)	109 (79)	139 (86)	156 (81)	21 (81)	14 (79)	1,601(54)	1,663 (48)
40–49	487 (70)	750 (68)	797 (78)	251 (76)	231 (81)	227 (80)	23 (83)	21 (62)	2,333 (58)	2,100 (51)
50–59[a]	816 (58)	1,285 (62)	1,239 (80)	406 (75)	325 (83)	283 (83)	26 (73)	41 (73)	3,573 (55)	3,084 (52)
Overall	1,701 (64)	2,600 (64)	2,349 (79)	766 (76)	695 (83)	666 (82)	70 (79)	76 (71)	7,507 (56)	6,847 (51)

[a] Note that controls may have been younger than 30 or older than 59 when matched to cases in the lowest or highest age groups

interviews was over 90%. However, in Italy and Norway respectively 39% and 48% of case interviews and 65% and 46% of control interviews were conducted by telephone. The patterns of telephone interviews amongst cases with the other tumour types were very similar (not shown).

The overall proportion of proxy respondents for glioma cases was 13%. This varied considerably across centres, from 2% to over 40% (Table 6). A small proportion of interviews was conducted with the study subject accompanied by another person. The proportion of proxy interviews was less than 2% for meningioma and even less for acoustic neurinoma and parotid gland cases. As would be expected, there were virtually no proxy respondents amongst the controls except in New Zealand where proxy interviews were conducted for the controls matched to cases who could not be interviewed themselves.

Overall, 60% of the face-to-face interviews with glioma cases were conducted at home, 33% in hospital, and 7% elsewhere (Web Annex Table 4). This varied greatly: in some centres, nearly all interviews were conducted at

Table 6 Distributions of interviews by mode of interview and interviewee, for glioma cases and all controls

Study centre	Total number of interviews		Percentage of interviews that were							
			Mode of interview				Interviewee			
			Face-to-face		Telephone		Subject alone or with another person		Proxy	
	Cases	Controls	Cases	Controls	Cases	Controls	Cases	Controls	Cases	Controls
Australia	301	669	99	98	1	2	86	100	14	0
Canada										
Montreal	65	234	95	94	5	6	63	98	37	2
Ottawa	25	180	92	100	8	0	84	100	16	0
Vancouver	80	239	100	100	0	0	98	100	3	0
Denmark	181	662	100	100	0	0	94	100	6	0
Finland	178	559	99	99	1	1	97	100	3	0
France	94	472	97	88	3	12	89	100	11	0
Germany	256	1190	100	100	0	0	90	100	10	0
Israel	180	599	99	99	1	1	81	100	19	0
Italy	118	340	61	35	39	65	56	95	44	5
Japan	60	287	100	100	0	0	98	100	2	0
New Zealand	84	172	100	100	0	0	79	88	20	12
Norway	180	278	52	54	48	46	69	100	31	0
Sweden	227	407	94	94	6	6	93	100	7	0
UK										
North	429	788	100	100	0	0	92	100	8	0
South	307	582	100	100	0	0	95	100	5	0
Total	2,765	7,658	94	95	6	5	87	99	13	1

home; in others, nearly all were in hospital. The distribution of interview location was similar for meningioma and acoustic neurinoma cases (not shown). In contrast, 7% of control interviews took place in hospital (mainly in Finland and, to a lesser extent in Norway and Sweden, where study subjects were invited to treatment institutions for interview), 70% in the subject's home and 22% elsewhere (Web Annex Table 4).

Quality of interviews

After an interview had been completed the interviewer recorded his or her impression of the reliability of information on a 5-point scale, overall and for each specific section. The percentage of subjects judged by the interviewer to be unresponsive or uncooperative overall was very low for both cases and controls (1.8 and 1.2% respectively), ranging by centre from 0 to 5.6% among glioma cases and up to 4.7% among controls. The percentages of cases and controls who were mobile phone users and were judged by the interviewer to have had little or no difficulty in remembering past phone use were 80, 86, 91 and 94%, respectively, among glioma, meningioma, acoustic neurinoma and parotid gland tumour cases, and 91% among controls (not shown).

Interviews were conducted by 230 different interviewers, the number ranging from 2 in Canada–Montreal to 39 in Denmark. About 35% of the interviewers conducted less than 20 interviews and 25% of the interviewers conducted fewer than 10, mostly with cases. While 84% of the subjects were interviewed by interviewers who had a balanced workload between cases and controls, the workload in three centres was particularly unbalanced (Web Annex Table 5).

Subjects available for analyses

Table 7 shows the number of cases and controls available for analysis, as well as the total number of matched sets by tumour type. Overall there were 2,765 glioma cases, 2,425 meningioma cases, 1,121 acoustic neurinoma cases, 109 malignant parotid gland tumour cases and 7,658 controls available for analysis. A total of 55 glioma, 15 meningioma, 17 acoustic neurinoma and 2 parotid gland tumour cases were excluded from matched analyses due to a lack of suitable controls. Conversely, 196 interviewed controls could not be matched to any cases.

Table 7 Number of cases and controls available for analysis and number of matched case–control sets, by tumour type and study centre

	Glioma			Meningioma			Acoustic neurinoma			Malignant parotid gland tumours		
	No. cases	No. controls	Matched sets[a]	No. cases	No. controls	Matched sets	No. cases	No. controls	Matched sets	No. cases	No. controls	Matched sets
Australia	301	669	297	255	669	253	127	669	127	7	669	7
Canada												
Montreal	65	234	65	48	234	48	33	234	33	9	234	9
Ottawa	25	180	25	15	180	15	17	34	17	6	180	6
Vancouver	80	239	80	31	239	31	34	72	34	13	239	13
Denmark	181	662	179	121	662	124	71	425	70	15	662	15
Finland	178	559	177	231	559	231	76	559	75	–[b]		
France	94	472	94	148	472	144	111	221	107	–		
Germany	256	1190	256	250	1190	250	67	144	67	–		
Israel	180	599	180	350	599	350	72	264	72	19	599	19
Italy	118	340	118	110	340	110	30	68	30	11	340	11
Japan	60	287	60	82	287	82	69	287	69	–		
New Zealand	84	172	83	54	172	52	20	32	17	–		
Norway	180	278	154	148	278	143	38	278	38	11	278	11
Sweden	227	407	222	184	407	184	102	361	102	18	251	16
UK												
North	429	788	421	180	788	173	102	185	94	–		
South	307	582	299	221	582	220	152	582	152	–		
Total	2,765	7,658	2,710	2,425	7,658	2,410	1,121	4,415	1,104	109	3,452	107

[a] The case to control ratio is one to one for glioma and meningioma, one to two for acoustic neurinoma and one to three for parotid gland tumours. Note that in Germany two matched controls were interviewed for each case of glioma and meningioma

[b] -Parotid gland tumours were not included in theses centres

Missing data

About 10% of glioma cases and about 5% of the other cases and of controls had some missing data concerning their history of mobile phone use (Table 8). The percentage varied across centres (ranging from 2.7 to 23.7% among glioma cases and 0.7 to 13.8% among controls).

Socio-demographic factors

The proportion of subjects in the lowest educational level was somewhat higher for cases than controls in several centres (Web Annex Table 6). There were little differences in marital status between cases and controls for all types of tumour. Women were less likely than men to be married (not shown).

Discussion

INTERPHONE is the largest case–control study of glioma, meningioma, acoustic neurinoma and parotid gland tumours to date. It was set-up to evaluate possible associations between RF exposure from mobile telephones and risk of these tumours. It focuses on mobile phone use, by far the largest source of exposure to RF fields in the general population. Comparing exposures from mobile phones with the wide array of existing RF devices is complicated because they depend, *inter alia*, on the output power, the frequency of the field emitted and proximity to the source. Sources at a distance, such as radio-TV transmitters and base stations, imply low levels of exposure [46]. Sources operated close to the human body entail the highest levels of exposure [47]. Other wireless applications such as cordless phones or wireless Internet (WLAN) systems are now very common; however, their peak output power is below the level of typical mobile phones. Cordless telephones have an average output power of the order of 10 mW for DECT and less for other technologies [46], compared to about 120 mW for mobile phones operating in GSM 900 for example.

In addition to providing information concerning risks related to mobile phone use, INTERPHONE provides the largest case–control source of data on other potential risk factors for the tumours of interest including medical and

Table 8 Proportion of subjects in each study centre for whom missing mobile phone use data were imputed—by case–control status

	Glioma		Meningioma		Acoustic neurinoma		Malignant parotid gland tumours		Controls	
	No. cases	% With imputed values	No. cases	% With imputed values	No. cases	% With imputed values	No. cases	% With imputed values	No. controls	% With imputed values
Australia	301	16.6	255	2.0	127	2.4	7	0.0	669	4.9
Canada										
Montreal	65	12.3	48	2.1	33	0.0	9	0.0	234	4.3
Ottawa	25	4.0	15	0.0	17	5.9	6	0.0	180	1.1
Vancouver	80	3.8	31	9.7	34	0.0	13	0.0	239	4.6
Denmark	181	8.8	121	9.6	71	5.6	15	6.7	662	6.3
Finland	178	12.4	231	10.8	76	5.3	–[a]		559	13.8
France	94	9.6	148	2.8	111	3.6	–		472	4.7
Germany	256	2.7	250	1.6	67	0.0	–		1,190	1.7
Israel	180	10.6	350	4.0	72	5.6	19	10.5	599	6.7
Italy	118	23.7	110	5.5	30	10.0	11	0.0	340	9.7
Japan	60	6.7	82	1.2	69	5.8	–		287	0.7
New Zealand	84	6.0	54	0.0	20	0.0	–		172	1.7
Norway	180	9.4	148	6.1	38	7.9	11	0.0	278	5.8
Sweden	227	14.5	184	13.0	102	12.7	18	11.1	407	7.6
UK										
North	429	7.9	180	2.2	102	2.0	–		788	3.4
South	307	12.1	221	2.7	152	5.3			582	6.4
Total	2,765	10.6	2,425	4.9	1,121	4.7	109	4.6	7,658	5.3

[a] -Parotid gland tumours were not included in these study centres

occupational exposure to EMF and to ionising radiation and medical history of subjects and their families.

To the extent possible, we standardised the design, procedures and materials across study centres. Some methodological variation across centres was unavoidable, however, in regard to approach to cases and controls, type of interview and mode of interview. The varying constraints of ethical committees influenced the methods of recruitment of cases and controls. In some centres quite a large proportion of cases was ascertained late through secondary sources. Because of this, a number of cases (particularly glioma) had died or were too ill to be interviewed and proxy respondents had to be found. A substantial proportion of interviews, particularly for controls, was conducted by phone to increase participation in some centres.

Case–control studies such as INTERPHONE are prone to various possible sources of error. These include possible selection bias related to non-participation amongst cases and controls; random and differential error in recall of mobile phone use; differences between cases and controls in timing of interviews in a period of dramatic increase of mobile phone use; and confounding by other potential risk factors for these diseases.

Selection bias

The INTERPHONE study is no exception to the apparently inexorable decline in participation rates amongst controls selected from the general population for epidemiological studies [48]. The source population is younger than in many other cancer studies and at an age when response rates tend to be lower. The youngest men proved particularly difficult to recruit. Another factor influencing the participation of controls is the difficulty of finding a sampling frame with sufficiently accurate, up-to-date and complete information, which resulted in large numbers of subjects who could not be traced or could not be contacted using the methods authorised by ethics committees.

The possibility that participation among controls might be selective with respect to phone use was of concern, given the low participation rate (53%). Mobile phone users could be over-represented among non-participating subjects as they may be more difficult to trace (fewer with listed telephone numbers for land-lines) or too busy to participate; this could lead to overestimation of the true OR. Alternatively, we have some evidence from the non-respondent questionnaires—which were completed by 57% of controls who refused to participate and may not be

representative of all non-participants in the study—that non mobile phone users may be more likely to refuse to participate, perhaps in the mistaken belief that non-users are of no interest to the study [49]. Such a bias could artificially increase the proportion of users among interviewed controls and reduce the likelihood of finding an effect should it exist. As ordained by local ethics committees, the presentation of the study differed somewhat by centre. We estimate that 41% of all controls were recruited in centres that used an approach in letters and information material that explicitly indicated that the primary objective concerned mobile phones, 46% were recruited in centres that mentioned mobile phones, without highlighting them, and 13% in the three centres that made no explicit mention of mobile phones. Thus there is a potential for differential participation between users and non-users and between users by level of use. The impact of a possible selection bias with respect to controls has been evaluated in a simulation study and shown to be potentially important [50]. Thus, it will have to be taken into account in interpreting the INTERPHONE results. In particular, analyses will be conducted by level of participation and by mode of presentation of the study.

Selection bias with regard to severity of illness may also arise in cases, particularly glioma cases. For example, as would be expected from the poor prognosis and strong impact on communication skills, the participation of glioma cases (65%) was less than that of patients with meningioma, acoustic neurinoma and malignant parotid gland tumours (78, 82 and 75% respectively). If RF exposure were related to the severity and prognosis of cancer, differential participation due to severe illness, early death or cognitive impairment could lead to bias. Despite considerable effort to ensure rapid ascertainment to avoid these difficulties, late ascertainment of a proportion of cases because of logistic reasons and, in some countries difficulties in complying with the requirements of ethics committees, resulted in lower participation than expected. Comparison of response by grade of tumour for gliomas, however, shows no major difference across study centres with different delays between diagnosis and interview. The possibility of severity or survival bias will nevertheless have to be considered when interpreting results.

Recall error

Self-reports of historical mobile phone use may be prone to substantial error. If such errors occur randomly, they usually bias risk estimates towards the null (no effect). They also increase the uncertainty of risk estimates, making it more likely that real associations are not detected. Results of short-term validation studies with volunteers indicate that recall of phone use is subject to moderate systematic error, but substantial random error: a substantial proportion of subjects markedly over- or under-estimated their mobile phone use [42].

Cases may spend time after the diagnosis of their tumour trying to understand why they have developed this disease, which might introduce a differential bias (sometimes referred to as rumination bias) in comparison with controls in recall of the amount and side of phone use. In addition, some of the patients with glioma might have recalled their phone use less accurately because of severe illness or cognitive impairment. Information about possible differences in recall of amount of use between cases and controls was obtained from retrospective validation studies. Analyses are underway and will be taken into account in the interpretation of results. The results of these analyses will be published separately.

Analyses of the INTERPHONE data will include various approaches to examining the potential for recall bias related to mobile phone use.

Other sources of bias

Possible confounding effects of region, age and sex will be taken into account systematically by the matching of cases and controls. Indeed, the mean ages of cases and controls are very close (glioma cases and controls 47.3 years; meningioma cases and controls 49.3 years; acoustic neurinoma 47.5 and 47.7 years respectively for cases and controls; parotid gland tumour cases and controls 46.3 years).

Because SES may well be correlated with mobile phone usage and with brain cancer risk [51], our primary indicator of SES, education status, will be included as a confounder in the analyses.

A priori, we do not have strong grounds for believing that other possible causes of the tumours studied, such as family history of brain tumour, past medical radiation exposure, smoking history and occupations in jobs with potential for ionising and non-ionising radiation exposure, would be related to mobile phone use. Nonetheless, the possibility of confounding by these factors will be examined empirically and they will be included in risk models where their inclusion results in a change in the ORs for the mobile phone use variables of 10% or more [52].

The fact that controls tended to be interviewed later than cases may also be a source of bias: because of the dramatic increase of mobile phone use during the study period, subjects interviewed later are more likely to have been mobile phone users. This will be handled by the matching, by truncating the exposure history of controls at the reference date, and, where appropriate, by adjustment of analyses for dates of interview and by analyses restricted to cases and matched controls interviewed close in time.

Symptoms of the disease could affect the use of mobile phones. Thus the year before diagnosis will not be included in the exposure period, and control exposure time will be truncated accordingly. For some tumours, however, early symptoms may appear much earlier. This will need to be considered carefully for acoustic neurinoma patients, as the early symptoms comprise hearing loss, tinnitus or buzzing sounds in the ear, which could lead patients to use mobile phones less frequently or to change the side of use.

There is also concern about the possibility of bias due to differences between cases and controls and between short term and long-term users in the extent of missing information and imputations for missing values were therefore conducted. Sensitivity analyses will be conducted excluding subjects with imputations, telephone and proxy interviews, and study subjects who were judged by the interviewer to be uncooperative or to remember their phone use poorly.

Differential assignment of cases and controls to interviewers in some centres and the use of many interviewers who conducted few interviews may be another potential source of bias. Sensitivity analyses will be conducted excluding interviewers with fewer than 20 interviews and those who interviewed nearly exclusively cases or controls.

Finally, despite the fact that INTERPHONE was jointly planned and based on a common core protocol, there was some heterogeneity in the methods used. Sensitivity analyses will be conducted excluding, in turn, different study centers. Additional analyses of patterns of results across study centres are planned to evaluate, in particular, the impact of the way the study was presented (whether a study of mobile phone use or a more general study) and of the participation levels among cases and controls. These will be helpful in addressing the potential for bias that might affect the overall findings.

Conclusions

Large, carefully conducted multi-centric international studies are an important source of information for the elucidation of the possible impact of mobile phone usage on cancer risk. This paper describes the complex methods used as well as the methodological hurdles that we have encountered. Particular attention was paid to errors and biases resulting from selection and non-participation of eligible subjects and from reporting of mobile phone usage. Different types of sub-studies were conducted to inform the analysis and interpretation of results.

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