

Guidelines for Application Priority Programme 'Physical Exercise and Cancer Patients'

Introduction

Physical exercise has shown positive effects in the prevention of various cancers and in the rehabilitation of cancer patients after primary treatment. In patients with advanced cancer, physical exercise is considered to have supportive and synergistic effects with palliative treatments. These benefits of physical exercise may be due to somatic as well as psychooncologic effects.

To date, systematic physical exercise is not yet fully integrated into standard oncological care. It is not yet reflected in clinical pathways, and there is insufficient awareness of the relevance of physical exercise by caregivers and patients alike.

This initiative of Deutsche Krebshilfe aims at supporting the development of routine treatment pathways that reflect the potential benefits of organized physical exercise for cancer patients. In order to enhance the acceptance of physical exercise by medical staff and patients, its details and effects should be analyzed for a better understanding of the underlying mechanisms of action as well as its prospective outcome.

Please notice that the focus of this programme is restricted to physical exercise **during** treatment.

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Guideline for Application

General Procedure

The procedure for application and evaluation consists of three steps. Prospective applicants have submitted a letter of intent to German Cancer Aid on 29 Jul 2011 and project outlines on 22 Aug 2011. The preliminary evaluation of the project outlines will be completed by the end of January 2012. If the preliminary evaluation is favourable, full applications must be submitted by **12 Apr 2012**, 13:00 to German Cancer Aid.

Application documents must contain the information and attachments as outlined below. Please use **all** reference numbers and corresponding titles as indicated in this guideline. If a chapter or point is not applicable, please designate it with 'not applicable', adding a brief explanation if necessary.

Please keep your application short and concise. Observe all given page limits (1 page corresponds to: 1 DIN A 4 page, single spaced, equivalent font to Arial, size 11pt).

Applications will be evaluated by an international evaluation team of experts. Please submit your application incl. attachments (e. g. CVs) in **English**. However, we ask you to submit the 'Project Title', the 'Summary', the 'Summary of requested funding' and the name of institutions of all applicants **also** in German.

Please submit **10 copies** of the application (one unbound version with original signatures and nine bound copies) no later than **29 Apr 2011**, 13:00 to the office of German Cancer Aid (e-mails and faxes are NOT accepted). Bound copies are intended to be sent to the experts of the evaluation team. Please note that bound copies are NOT checked for completeness by Cancer Aid Office.

Please also include a CD-ROM with the following files:

- the complete application as **one** pdf-file, including signatures and attachments (maximum 8 MB)
- information on chapters 1 and 3 ('General Information' and 'Summary') as a Word- or RTF-document

Please submit all required documents by post to the office of German Cancer Aid:
Deutsche Krebshilfe e. V.
Abteilung Förderung
Buschstraße 32
53113 Bonn

Within two weeks of receipt of the application by the Cancer Aid Office, the applicant/ coordinator will receive a written confirmation of receipt, together with a reference number. If you fail to receive confirmation of receipt, please send an e-mail to the Funding Department of German Cancer Aid (foerderung@krebshilfe.de), giving the full project title and your telephone number.

If you have any questions, please contact:

Eva Grierson, 0228 / 72990-228, e-mail: grierson@krebshilfe.de
Annika Thiel, 0228 / 72990-220, e-mail: annika.thiel@krebshilfe.de

1. General Information

1.1 Applicant(s)/Coordinating Investigator (in English)

We wish to point out that applications are not accepted from members of profit-making organisations or from persons not permitted to publish results in a generally accessible form.

All applicants are expected to provide the following information:

- First name, surname, academic degree, date of birth
- Full name of the institution/organisation
- Postal address
- Telephone and fax numbers, e-mail address
- Reference numbers of all previous applications to German Cancer Aid for project funding

If your application is submitted by several applicants or by an interdisciplinary consortium, please indicate the person assigned for corresponding with German Cancer Aid as the coordinator on behalf of all applicants or the consortium.

Please inform us at once if you change your address.

1.2 Applicant(s)/Coordinating Investigator (in German)

Please provide the following information also in German:

- Full name of the institution/organisation of each applicant

1.3 Study Synopsis

Give a synopsis of your planned study, using this tabular form:

Project title (in English)	(maximum 160 characters)
Project title (in German)	(maximum 160 characters)
Objective(s)/Hypotheses	Which principal research questions are to be addressed? Specify clearly the primary hypotheses of the trial that determine sample size calculation.
Intervention(s)	Description of the experimental and the control treatments or interventions as well as dose and mode application. <ul style="list-style-type: none"> • Experimental intervention • Control intervention • Duration of intervention per patient
Study population	<ul style="list-style-type: none"> • Key inclusion criteria • Key exclusion criteria
Outcome(s)	<ul style="list-style-type: none"> • Primary efficacy endpoint • Key secondary endpoint(s)
Duration of treatment and follow-up	<ul style="list-style-type: none"> • Duration of treatment per patient • Follow-up per patient
Study type	e. g. Randomized/non-randomized, parallel group/cross-over.
Statistical analysis	<ul style="list-style-type: none"> • Efficacy • Description of the primary efficacy analysis and population • Safety • Secondary endpoints

Sample size	<ul style="list-style-type: none"> • To be assessed for eligibility (n=) • To be allocated to trial (n=) • To be analysed (n=)
Trial Duration	Duration of the entire trial (First patient in to last patient out, Recruitment period).
Participating centres	How many centres will be involved? (n=)

2. Table of contents with page numbers

Please indicate each chapter with page numbers, using all reference numbers and corresponding titles as given in these guidelines.

3. Summary

3.1 Summary of the project (in English)

Please give a short description of the whole project, including the aims and objectives. The summary must not be longer than 1 page. It will be included in the submissions for the expert committees and advisory boards.

3.2 Summary of the project (in German)

(see 3.1)

4. Information on the proposed project

Chapter 4 must not exceed 12 pages.

4.1 Background/State of the art

Give a brief description of the primary research focus or foci of the host institutes, in order to illustrate the setting in which the research will take place.

Summarise the relevant literature, from which the research question for the current application emerges. Which oncological problem is to be addressed? What is the novel aspect of the proposed trial? Which principal research questions are to be addressed? Bring them into order indicating major and minor motivations/starting hypotheses of the investigation planned.

Please also set your trial into perspective. Which trials have already been conducted and what is the relevance of their results? Give references to any relevant systematic review(s) and/or feasibility studies, relevant previous/ongoing trials. However, the text should be comprehensible without reading the cited articles.

4.2 Own preliminary work

Preliminary work of the applicants should be specified completely, including a description of expertise and capacities in managing interventional studies.

You might also like to refer to the most important publications of the applicant(s) which are specifically related to the subject or methods of the proposed project. However, a complete list of the current publications of the applicant(s) should be added as an attachment to your proposal (see chapter 10.2 of these guidelines).

4.3 Expected Results

Present a brief description of the objectives, hypotheses as well as the outcomes of the planned project. Are the chosen endpoints/outcome measures suitable? Which results will be of immediate value for the patient and how could they be implemented in clinical practice? What is the perspective after your project is finished?

4.4 Plan of investigation

Provide a detailed but concise description of the planned project to be conducted during the application period. The quality of the work schedule is of critical importance in deciding whether the project deserves funding. Give detailed information on the following criteria:

- Study population
- Study design
- Interventions
- Data collection procedure
- Outcome measures
- Sample size calculation
- Statistical analyses

4.5 Time schedule and milestones

Please present a time-table/flow chart of the study. Set measurable milestones and describe them.

5. Requested Funding

5.1 Personnel

The following information is needed:

- Designation of the requested position (e.g. 'Scientific Assistant', 'Technician', 'Doctoral Student', 'Physician')
- The requested duration of employment (e.g. 'for 3 years')
- The salary grade according to the Wage Agreements for Public Employees (TVöD, TV-L, TV-Ä; please do **not** give payments in Euros for staff members, Cancer Aid Office will calculate the necessary personnel funds)
- An exact description of the duties of each position requested (a reference to the work schedule is not sufficient)
- If the persons requested are already known to you, please indicate their names

5.2 Funds for equipment/non-recurring investments

In particular, this includes scientific instrumentation.

The following information is required:

- The name of the equipment or instrument
- Purchasing price in € including VAT, deducting discounts, together with a current tender or cost estimate from a possible supplier (copies of company catalogues or an Internet page are not accepted)

- A detailed explanation of why you need the requested instruments to perform the project, with reference to currently available equipment

Please bear in mind that German Cancer Aid does not in principle fund instruments which are part of the basic equipment of an institute or hospital.

5.3 Funds for consumables

Please describe the consumables (e.g. questionnaires), with the annual costs in € of each item requested.

5.4 Travel expenses

Funds can be requested for travel which is absolutely essential for the successful completion of the project (e.g. travel to collaboration partners). If you are applying for travel expenses, please state the amount on each position and justify the necessity.

5.5 Other costs

These include, for example, commissions to third parties.

5.6 Summary of requested funding (in English)

Application period: x years

(PLEASE NOTE: if your project includes several working groups at different institutions which require separate financial administration, please give a separate summary for each working group.)

Personnel:

1 _____ Scientific Assistant, TV-L 13, for x years (for Dr. ...)

1 _____ Technician, TV-L 8, for x years (N.N.)

Equipment (non-recurring):

1 _____ Instrument € _____

1 _____ Instrument € _____

_____ € TOTAL

Consumables:

- For € _____

- For € _____

_____ € TOTAL

Travel expenses:

- For travels to collaboration partners € _____

_____ € TOTAL

Other costs:

- For € _____

- For € _____

_____ € TOTAL

5.7 Summary of requested funding (in German)

Beantragte Förderungsdauer: x Jahre

(PLEASE NOTE: if your project includes several working groups at different institutions which require separate financial administration, please give a separate summary for each working group.)

Personalmittel

1 Wiss. Mitarbeiter/in, TV-L 13, für x Jahre (für Dr. ...)

1 Techn. Assist., TV-L 8, für x Jahre (N.N.)

Investitionsmittel (einmalig)

1 Gerät €

1 Gerät €

€ TOTAL

Mittel für Verbrauchsmaterialien

- Für €

- Für €

€ TOTAL

Reisemittel

- Für Reisen zu Kooperationspartnern €

€ TOTAL

Mittel für Sonstiges

- Für €

- Für €

€ TOTAL

6. Prerequisites for carrying out the project

6.1 Your team

Please indicate name, academic degree and professional position of all participants (scientists, assistants, employees) who may work on the planned project. Please give a short and well-defined description of the duties of each project participant. Indicate the contribution of each project participant to the project, including applicant(s), as percentage of their working hours.

6.2 Collaborations

Please only name those scientists, physicians or other collaboration partners with whom you have or have agreed on specific collaboration in the project for which funding is requested. Please attach a written statement of intent for each collaboration partner.

6.3 Collaboration with companies

Please state whether you are cooperating with an industrial partner as part of the planned project and, if so, to what extent. Include the confirmation of the industrial partner.

6.4 Statistical expertise

A statistician, biometrician or scientist with corresponding qualifications must be closely involved in carrying out the project. Please state the name, institution and qualification of the responsible statistician/scientist. In case he/she is not an applicant, please include a signed statement.

6.5 External data sources

In case you plan to include external data sources for your project, please give written proof that they are available for the study.

6.6 Equipment available

Please provide information about the scientific instrumentation and equipment on site which is available to you for the project.

6.7 Your institution's contribution to basic equipment

Please indicate the contribution of the participating institution(s) to the basic equipment (e.g. provision of personnel, of funds for consumables or of equipment for the planned project).

7. Further particulars

7.1 Statement of the ethics committee (if necessary)

A statement on the planned research project from the ethics committee of your institution is necessary, if investigations are to be performed in individual persons (e.g. qualitative interviews, if individual personal data are involved), or if human material (e.g. blood or tissue sample) is used. The statement of the ethics committee must make it clear that there are no reservations about conducting the project applied for funding by German Cancer Aid. Include the statement of the ethics committee as an attachment or, if applicable, write that the ethics committee statement will be submitted subsequently. Approval of the study by the ethics committee must be available before the start of the project funding.

If several sites are involved in the research project for which funding is requested, corresponding statements from the responsible ethics committees may have to be presented.

7.2 Third party funding

A list of all third party funding which the applicants receive at the time of the application (i.e. **current** third party funding) - containing each project title, the source of funding, the duration, start and end date of funding. Please also list all planned projects for which you have applied for funding, each with the project title and the funding organisation to which you have applied.

8. Declaration

German Cancer Aid must be informed if you have submitted the application or parts hereof to another funding organisation before.

In all cases, the following declaration must be made:

'A request for funding this or a similar project has not been submitted to any other addressee. The same or a similar request for funding will not be submitted to other institutions during the review process. German Cancer Aid reserves the right to inquire at other funding organisations about the submission of this or a similar application and to request further information hereof.'

9. Signature(s)

Place, date and original signatures of all applicants.

10. Attachments

The following attachments are to be included with the application. Please remember to include the attachments with each copy of the application as well as with the pdf-version.

10.1 Curriculum vitae

Curricula vitae of all applicants, emphasising their scientific careers (table format).

10.2 Current list of publications

Please give a list of all articles published by the applicants within the last five years. Publications which have not yet appeared should be designated as 'in print in..', 'accepted by..' or 'submitted to...'. Manuscripts may be included as an attachment. Please do not include any publications which are still in preparation.

10.3 Approval of the application by the head of the institution

Please attach a signed approval from the director or head of the institution/organisation at which the project in the application is to be performed. This should clarify that the director or head of the unit has been informed of the application and agrees that the project can be conducted with participation of the applicant. This approval must not be submitted if the director or head of the unit is himself the applicant. If the project is to be performed at several institutions/organisations, equivalent approvals may have to be submitted by the heads of all units involved.

10.4 Statement(s) of the ethics committee(s) (if necessary)

These can be submitted later, see chapter 7.1.

10.5 Letters of Intent

Attach all letters of intent by scientific or industrial collaboration partners, see chapters 10.26.2, 6.3, 6.4 and 6.5.

10.6 Further attachments

e.g. reprints and manuscripts

11. Further information

- We wish to point out that the acceptance of funding obligates the recipient(s) to comply with the rules of good scientific practice. The rules of good scientific practice are described in detail in the German Research Foundation's Guidelines for the Use of Funding (DFG forms 2.01 or 2.02, www.dfg.de/formulare).

In the event of scientific misbehaviour, sanctions may be taken. In particular, scientific misbehaviour is present when false information is supplied in a scientific context, either deliberately or as the result of gross negligence, the intellectual property of others is violated or their research work is impaired. The circumstances of the individual case are decisive.

- German Cancer Aid reserves the right to disclose information on the application (name of the applicant(s), topic and objectives of the planned project) to other funding organisations in order to avoid double funding.
- A submission of application to German Cancer Aid does not constitute a legal claim to funding. Furthermore, the applicant has no right to claim the return of the application.