

The Protocol Support Tool

Protocol Support Tool v1

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About the Protocol Support Tool

PST

The Protocol Support Tool or PST is a tool that supports the production of a high quality research protocol. It provides a checklist of issues that should be considered when writing a protocol, examples of how these issues have been addressed by other researchers and a library of full protocols. It also provides access to a website of other resources and tools.

Documents and resources that are contained within PST will have an **PST..!** icon next to it. Resources that require an Internet connection are marked with an **Web** icon.

PST has been developed by the EC-funded Pragmatic Trials in Health Care (Practihc) project. PST runs on Windows 95 and higher. Suggestions for improvements are welcome and should be addressed to practihc@gwmail.jr2.ox.ac.uk

This page was last updated 27th December 2002.

Some PST guidelines from the Cape Town meeting

- Must be as small as possible.
- Be able to run without an Internet connection.
- Be simple to use.
- Be expandable.
- Would be an advantage if it could run on several platforms and could be linked to EpiInfo.
- Support multiple languages.

The current PST

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About the Protocol Support Tool

PST

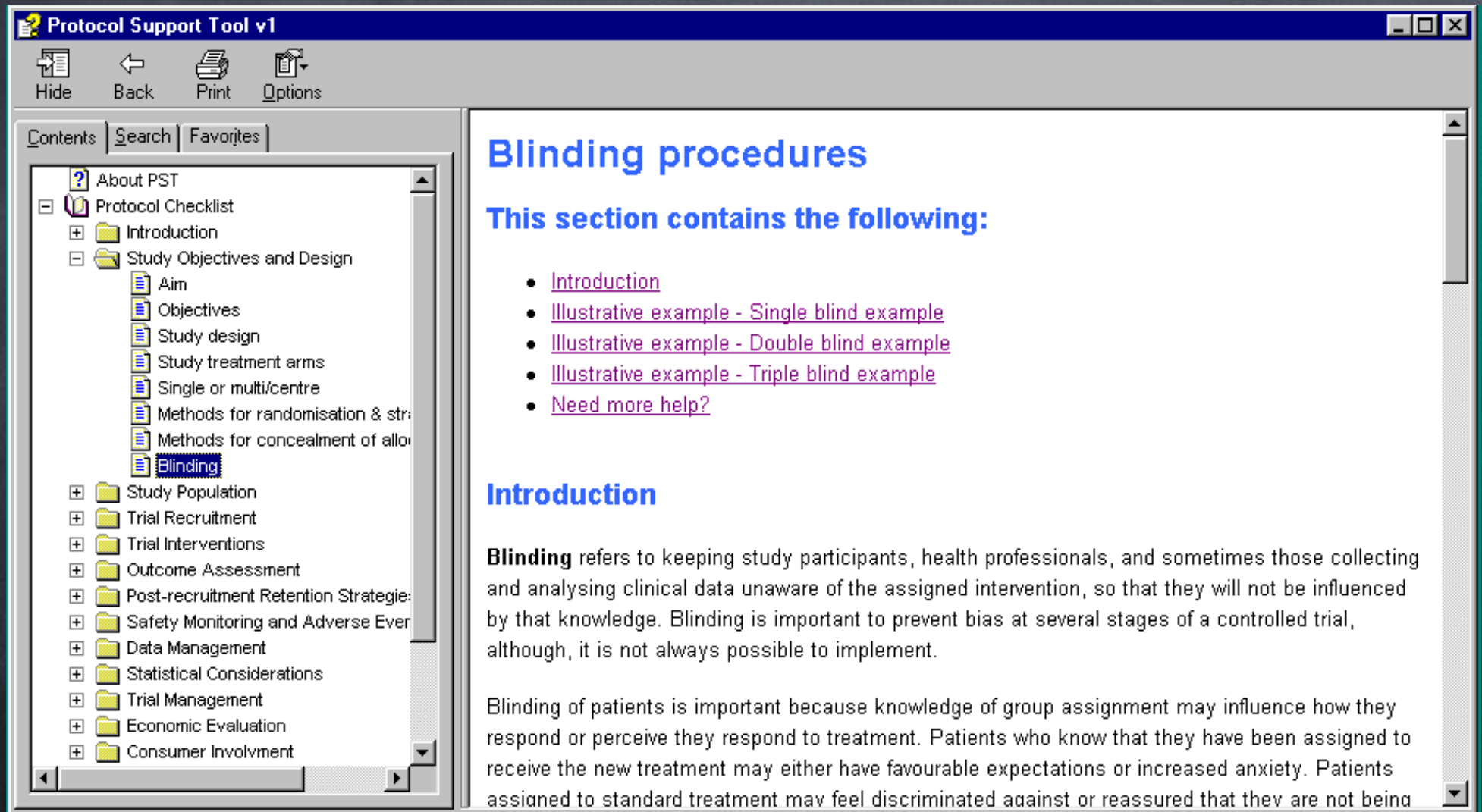
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PST works like a normal Help system



The screenshot shows a window titled "Protocol Support Tool v1" with a menu bar containing "Hide", "Back", "Print", and "Options". Below the menu bar are tabs for "Contents", "Search", and "Favorites". The "Contents" tab is active, displaying a tree view of the help system. The tree view includes "About PST", "Protocol Checklist", and several folders. The "Protocol Checklist" folder is expanded, showing sub-items like "Introduction", "Study Objectives and Design", "Study Population", "Trial Recruitment", "Trial Interventions", "Outcome Assessment", "Post-recruitment Retention Strategies", "Safety Monitoring and Adverse Events", "Data Management", "Statistical Considerations", "Trial Management", "Economic Evaluation", and "Consumer Involvement". The "Blinding" document is selected and highlighted in blue. The main content area displays the "Blinding procedures" section, which includes a list of sub-topics and an introduction paragraph.

Blinding procedures

This section contains the following:

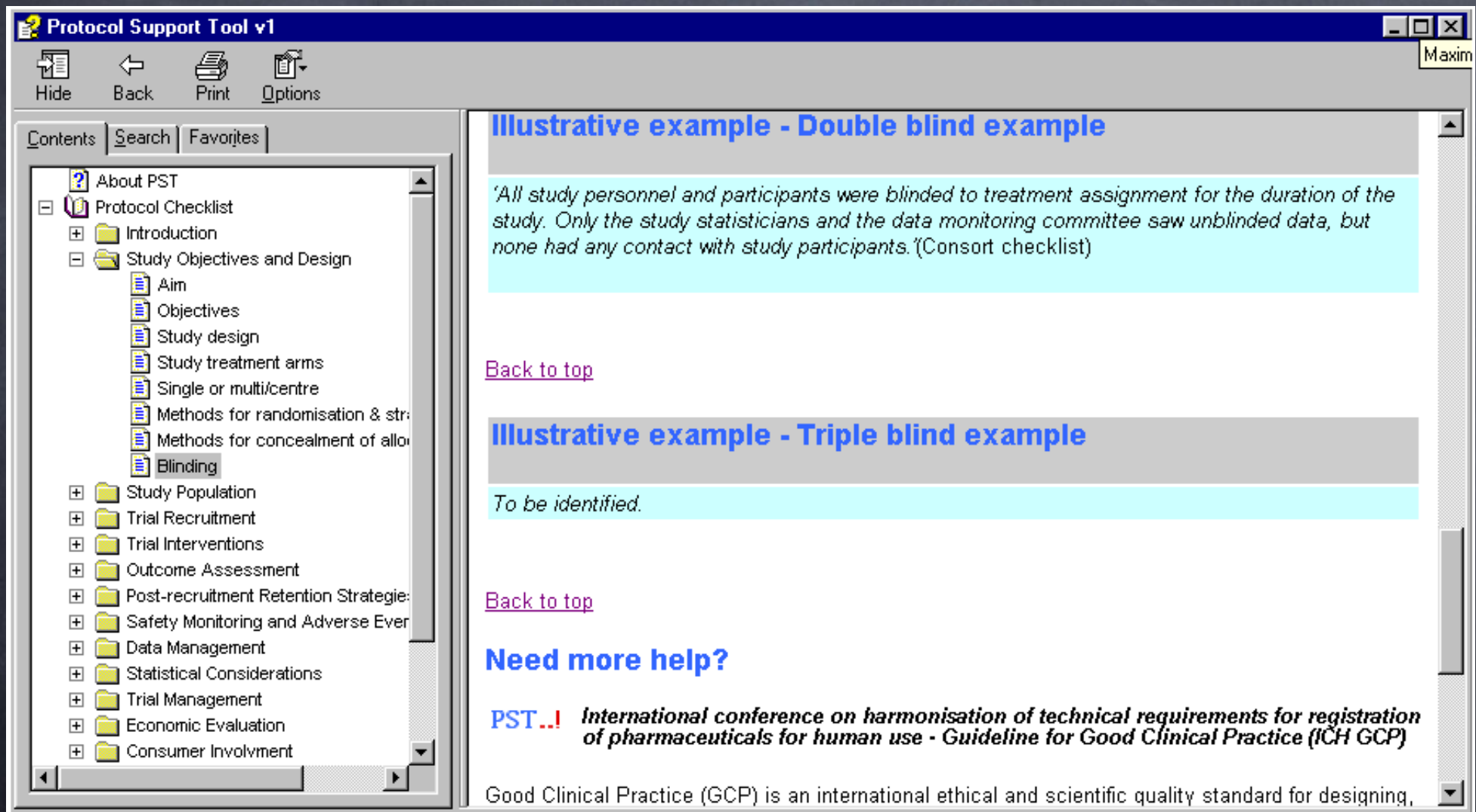
- [Introduction](#)
- [Illustrative example - Single blind example](#)
- [Illustrative example - Double blind example](#)
- [Illustrative example - Triple blind example](#)
- [Need more help?](#)

Introduction

Blinding refers to keeping study participants, health professionals, and sometimes those collecting and analysing clinical data unaware of the assigned intervention, so that they will not be influenced by that knowledge. Blinding is important to prevent bias at several stages of a controlled trial, although, it is not always possible to implement.

Blinding of patients is important because knowledge of group assignment may influence how they respond or perceive they respond to treatment. Patients who know that they have been assigned to receive the new treatment may either have favourable expectations or increased anxiety. Patients assigned to standard treatment may feel discriminated against or reassured that they are not being

Just click on the links, eg. an illustrative example



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 - Methods for concealment of allocation sequence
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 - Safety Monitoring and Adverse Events
 - Data Management
 - Statistical Considerations
 - Trial Management
 - Economic Evaluation
 - Consumer Involvement

Illustrative example - Double blind example

'All study personnel and participants were blinded to treatment assignment for the duration of the study. Only the study statisticians and the data monitoring committee saw unblinded data, but none had any contact with study participants.'(Consort checklist)

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Illustrative example - Triple blind example

To be identified.

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Need more help?

PST..! *International conference on harmonisation of technical requirements for registration of pharmaceuticals for human use - Guideline for Good Clinical Practice (ICH GCP)*

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing,

PST contains several types of document

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 - Sample size justification
 - Dummy tables
 - Compliance and missing data
 - Interim analyses
 - Statistical analysis
 - Trial Management
 - Economic Evaluation
 - Consumer Involvement
 - Reporting, Dissemination and Notification
 - References

PST..! *Software for performing a sample size calculation for binary outcomes*

An [Excel spreadsheet](#) for performing sample size calculations for binary outcomes.

PST..! *Software for performing a sample size calculation for continuous outcomes*

An [Excel spreadsheet](#) for performing sample size calculations for continuous outcomes.

PST..! *Software for performing a sample size calculation for binary outcomes in a cluster trial*

An [Excel spreadsheet](#) for performing sample size calculations for binary outcomes in cluster trials.

PST..! *Software for performing a sample size calculation for continuous outcomes in a cluster trial*

An [Excel spreadsheet](#) for performing sample size calculations for continuous outcomes in cluster trials.

PST..! *Database of intraclass correlation coefficients*

Excel spreadsheets for example

Sample size calculator
(binary outcome)

This spreadsheet is designed to calculate the number of participants required for a two-arm randomised controlled trial comparing two PROPORTIONS

The user must enter:

- the proportion in the control group (0.2 or 0.3 etc) AND
- the proportion in the intervention group (0.4 or 0.5 etc)

The number of participants required in each group is calculated with 80% power and 5% significance

BINARY OUTCOME

Control group proportion = *enter value here(eg 0.2)

Intervention group proportion = *enter value here(eg 0.3)

Number per group = (80% power; 5% significance;two-sided test)

..and pdfs

Acrobat Reader - [CONSORT.pdf]

File Edit View Tools Window Help

CONSORT STATEMENT

CONSORT statement

The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials

*David Moher, Kenneth F Schutz, Douglas G Altman, for the CONSORT Group**

To comprehend the results of a randomised controlled trial (RCT), readers must understand its design, conduct, analysis, and interpretation. That goal can be achieved only through total transparency from authors. Despite several decades of educational efforts, the reporting of RCTs needs improvement. Investigators and editors developed the original CONSORT (Consolidated Standards of Reporting Trials) statement to help authors improve reporting by use of a checklist and flow diagram. The revised CONSORT statement presented here incorporates new evidence and addresses some criticisms of the original statement. The checklist items pertain to the content of the Title, Abstract, Introduction, Methods, Results, and Discussion. The revised checklist includes 22 items selected because empirical evidence indicates that not reporting this information is associated with biased estimates of treatment effect, or because the information is essential to judge the reliability or relevance of the findings. We intended the flow diagram to depict the passage of participants through an RCT. The revised flow diagram depicts information from four stages of a trial (enrolment, intervention allocation, follow-up, and analysis). The diagram explicitly shows the number of participants, for each intervention group, included in the primary data analysis. Inclusion of these numbers allows the reader to judge whether the authors have done an intention-to-treat analysis. In sum, the CONSORT statement is intended to improve the reporting of an RCT, enabling readers to understand a trial's conduct and to assess the validity of its results.

A report of a randomised controlled trial (RCT) should convey to the reader, in a transparent manner, why the study was undertaken, and how it was conducted and analysed. Inadequately reported randomisation, for example, has been associated with bias in estimating the effectiveness of interventions.^{1,2} To assess the strengths and limitations of an RCT, readers need and deserve to know the quality of its methods.

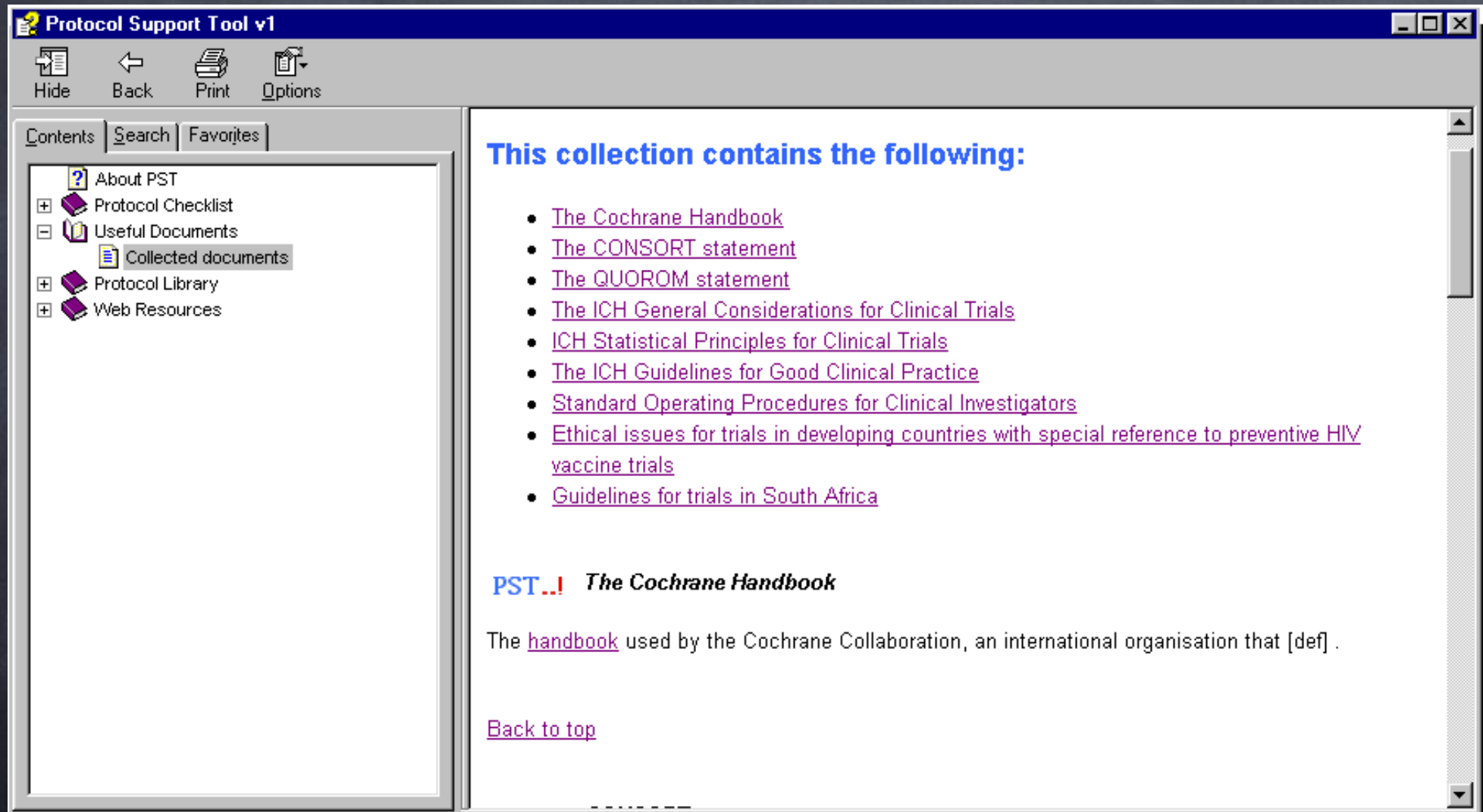
Despite several decades of educational efforts, RCTs are still not being reported adequately.^{3,4} For example, a review⁵ of 122 recently published RCTs that assessed the effectiveness of selective serotonin reuptake inhibitors as a first-line management strategy for depression found that only one paper described randomisation adequately.

international group of clinical trialists, statisticians, epidemiologists, and biomedical editors. CONSORT has been supported by a growing number of medical and health-care journals^{6,7} and editorial groups, including the International Committee of Medical Journal Editors (ICMJE, The Vancouver Group),⁸ the Council of Science Editors (CSE), and the World Association of Medical Editors (WAME). CONSORT is published in Dutch, English, French, German, Japanese, and Spanish. It can be accessed together with other information about the CONSORT group on the internet.⁹

The CONSORT statement consists of a checklist and flow diagram for reporting an RCT. For convenience, the checklist and diagram together are called simply

Page 1 of 4 100% 8.26 x 11.69 in

Some documents are collected together



The screenshot shows a web browser window titled "Protocol Support Tool v1". The interface includes a navigation bar with "Hide", "Back", "Print", and "Options" buttons. Below this is a "Contents" sidebar with a tree view containing: "About PST", "Protocol Checklist", "Useful Documents" (expanded to show "Collected documents"), "Protocol Library", and "Web Resources". The main content area is titled "This collection contains the following:" and lists ten items as bullet points, each with a purple underlined link. Below the list is a section for "PST..! The Cochrane Handbook" with a brief description and a "Back to top" link.

This collection contains the following:

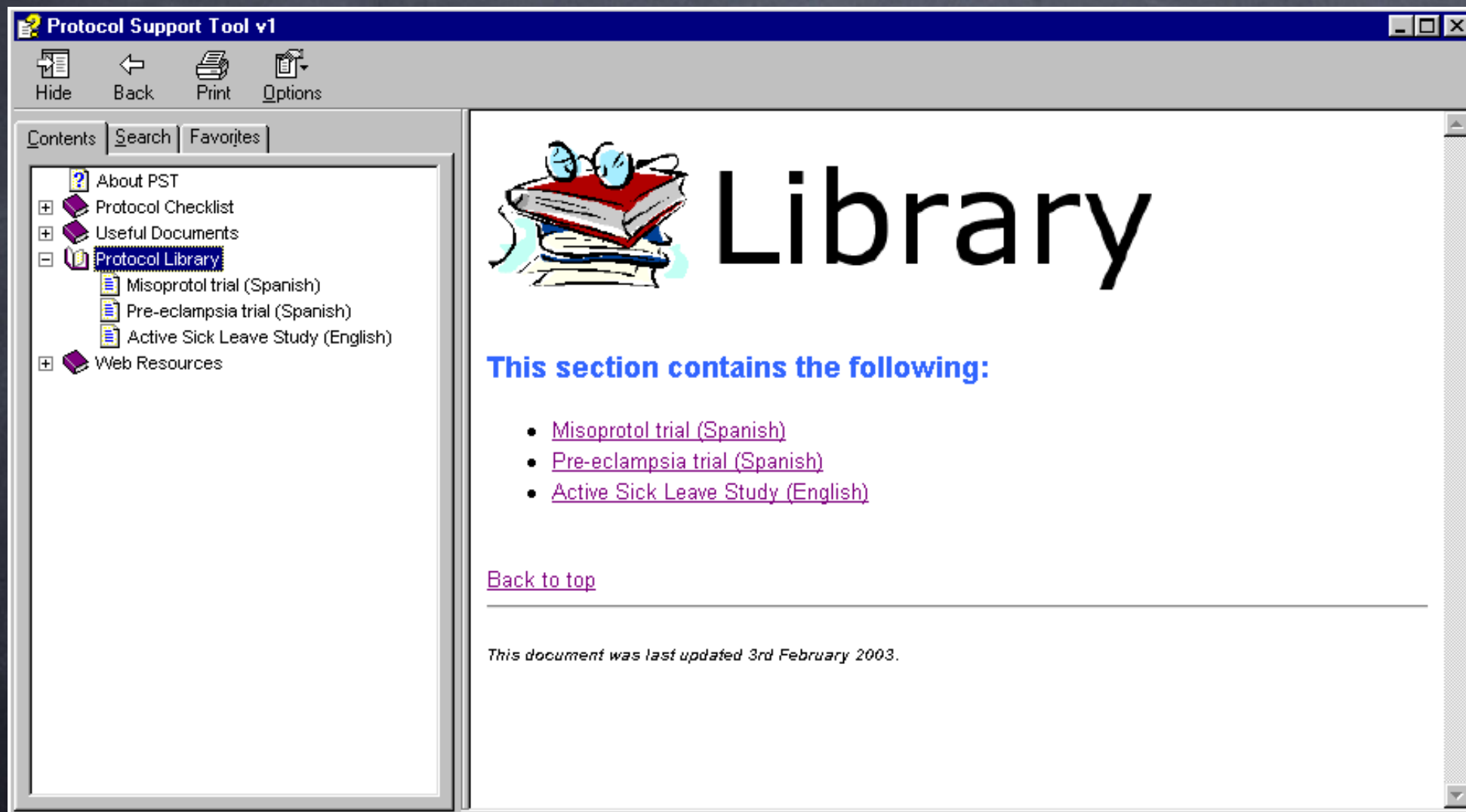
- [The Cochrane Handbook](#)
- [The CONSORT statement](#)
- [The QUOROM statement](#)
- [The ICH General Considerations for Clinical Trials](#)
- [ICH Statistical Principles for Clinical Trials](#)
- [The ICH Guidelines for Good Clinical Practice](#)
- [Standard Operating Procedures for Clinical Investigators](#)
- [Ethical issues for trials in developing countries with special reference to preventive HIV vaccine trials](#)
- [Guidelines for trials in South Africa](#)

PST..! *The Cochrane Handbook*

The [handbook](#) used by the Cochrane Collaboration, an international organisation that [def] .

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There is also a library of protocols



The screenshot shows a web browser window titled "Protocol Support Tool v1". The interface includes a navigation bar with "Hide", "Back", "Print", and "Options" buttons. Below this is a "Contents" sidebar with a tree view containing "About PST", "Protocol Checklist", "Useful Documents", "Protocol Library" (highlighted), and "Web Resources". The "Protocol Library" section is expanded to show "Misoprotol trial (Spanish)", "Pre-eclampsia trial (Spanish)", and "Active Sick Leave Study (English)". The main content area features a "Library" header with an illustration of books and glasses, followed by a blue heading "This section contains the following:" and a bulleted list of the same three items. A "Back to top" link and a footer note "This document was last updated 3rd February 2003." are also present.

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- About PST
- Protocol Checklist
- Useful Documents
- Protocol Library**
 - Misoprotol trial (Spanish)
 - Pre-eclampsia trial (Spanish)
 - Active Sick Leave Study (English)
- Web Resources

Library

This section contains the following:

- [Misoprotol trial \(Spanish\)](#)
- [Pre-eclampsia trial \(Spanish\)](#)
- [Active Sick Leave Study \(English\)](#)

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This document was last updated 3rd February 2003.

Protocols are available in HTML and pdf formats

...promedio es más alta que lo estimado y es probable que sea alrededor de 400-500 ml. Por lo tanto, en un estudio donde se mide la pérdida de sangre, se considera más confiable elegir la pérdida de sangre mayor o igual a 1000 ml como punto de corte para HPP significativa.

Una tasa de HPP de 2-3 % con el uso de ocitócicos de rutina es una estimación conservadora dadas las tasas de los estudios publicados. Las siguientes tablas (1 y 2) indican que para que el estudio tenga un poder adecuado para demostrar un nivel de eficacia comparable con el misoprostol y detectar cualquier diferencia significativa con respecto a los efectos colaterales, se necesita reclutar alrededor de 20.000 mujeres (dos lados).

Tabla 1: Tamaño muestral necesario en distintos índices de HPP severa

Pérdida de sangre \geq 1000 ml con oxitócico estandar	2,00%	3,00%	2,00%
Nivel de pérdida de sangre comparable con misoprostol	2,75%	3,75%	2,70%
Poder	90%	90%	90%
Nivel alfa	5%	5%	5%
Razón de riesgo	1,38	1,25	1,35
Tamaño muestral (total)	17.850	24.894	20.248

Tabla 2: Poder estadístico del estudio con un tamaño muestral fijo de 20.000 mujeres (HPPS= HPP severa \geq 1000 mls)

Evaluating the PST

- We would like you to play with the PST in small groups.
 - Remember that not all sections are complete.
 - Use the evaluation form to focus your discussion.
 - Be honest. We can still change things.
-
- Return the forms to one of us (Kirsty, Craig, Marion or myself)

Checklist points with most content

- Introduction
- Study Objectives and Design
- Study Population
- Trial Recruitment
- Trial Interventions
- Statistical Considerations